CAROLYN B. MALONEY, NEW YORK
CHAIRWOMAN

ONE HUNDRED SEVENTEENTH CONGRESS

JAMES COMER, KENTUCKY
RANKING MINORITY MEMBER

Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND REFORM
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6143
MAJORITY (202) 225–5051
MINORITY (202) 225–5074
https://oversight.house.gov

March 24, 2022

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

I wrote to you earlier this week regarding the Food and Drug Administration's (FDA) failure to protect Americans from a heart pump device associated with over 3,000 deaths. I am now writing to request information about FDA's delayed response in addressing contaminated infant formula now linked to five hospitalizations and two deaths. According to public reporting, FDA learned in September 2021 about contaminated formula produced at an Abbott Nutrition facility in Sturgis, Michigan, but failed to issue a public warning until February.[1] Newly released FDA inspection reports show that Abbott Nutrition failed to maintain sanitary conditions and procedures at the plant for years.[2] FDA must do more to protect vulnerable infants from foodborne illnesses and warn their caregivers of potential dangers.

FDA was first on notice of the contaminated formula in September 2021, when Minnesota health authorities alerted FDA that they had traced one infant's *Cronobacter sakazakii* infection back to formula produced at the facility.[3] *Cronobacter sakazakii* infections

[1] *FDA Learned of Suspected Infant Formula Illness Four Months Before Recall*, Politico (Feb. 18, 2022) (online at www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226); Food and Drug Administration, *FDA Warns Consumers Not to Use Certain Powdered Infant Formula Produced in Abbott Nutrition's Facility in Sturgis, Michigan* (online at www fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutritions-facility) (accessed March 16, 2022) (as of FDA's February 17 announcement, formula was linked to four hospitalizations and was a potential cause of one death; on February 28, formula was linked to a fifth hospitalization and second death).

[2] *Plant Behind Abbott Baby Formula Recall Was Unsanitary, FDA Finds*, CBS News (Mar. 23, 2022) (online at www.cbsnews.com/news/abbott-baby-formula-recall-fda-details/).

[3] *FDA Learned of Suspected Infant Formula Illness Four Months Before Recall*, Politico (Feb. 18, 2022) (online at www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226).

are rare, but can lead to severe and life-threatening illnesses, including sepsis and meningitis.[4] When *Cronobacter sakazakii* causes meningitis, the mortality rate can be as high as 44%.[5]

FDA inspected the Abbott facility in late September and noted unsanitary conditions at the plant, but did not issue a warning.[6] FDA received two more reports of *Cronobacter sakazakii* infections tied to the facility between September and December, and also received a complaint about a *Salmonella* Newport illness linked to the facility.[7] FDA finally issued a warning to consumers on February 17, when Abbott voluntarily recalled the formula.[8] As of February 17, FDA knew the *Cronobacter sakazakii* and *Salmonella* Newport infections had led to four hospitalizations and may have contributed to one death. On February 28, the Centers for Disease Control and Prevention announced a fourth *Cronobacter sakazakii* infection linked to the facility, which may have contributed to a second death.[9]

Between January 31 and March 18, 2022, FDA again inspected the facility. Shockingly, FDA found that the Abbott facility failed to maintain clean surfaces for handling formula. FDA also found a history of *Cronobacter sakazakii* contamination at the plant, including eight such instances between 2019 and 2022.[10]

FDA is tasked with protecting all Americans from life-threatening foodborne illness outbreaks, but fell short in protecting vulnerable infants from contaminated formula. FDA must do more to ensure no lives are lost, or babies sickened, due to delayed inspections and late consumer warnings.

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[4] Food and Drug Administration, *FDA Investigation of Cronobacter Infections: Powdered Infant Formula* (online at www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022) (accessed Mar. 23, 2022).

[5] Margaret Taylor et al., *Two Cases of* Cronobacter Sakazakii *Meningitis in Infants* (Sept. 2021) (online at https://journals.lww.com/pidj/Fulltext/2021/09000/Two_Cases_of_Cronobacter_Sakazakii_Meningitis_in.20.aspx).

[6] *Plant Behind Abbott Baby Formula Recall Was Unsanitary, FDA Finds*, CBS News (Mar. 23, 2022) (online at www.cbsnews.com/news/abbott-baby-formula-recall-fda-details/).

[7] *FDA Learned of Suspected Infant Formula Illness Four Months Before Recall*, Politico (Feb. 18, 2022) (online at www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226).

[8] *Id.*; Food and Drug Administration, *FDA Warns Consumers Not to Use Certain Powdered Infant Formula Produced in Abbott Nutrition's Facility in Sturgis, Michigan* (online at www fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutritions-facility) (accessed March 16, 2022); Food and Drug Administration, *Company Announcement: Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant* (Feb. 17, 2022) (online at www fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant).

[9] Food and Drug Administration, *FDA Warns Consumers Not to Use Certain Powdered Infant Formula Produced in Abbott Nutrition's Facility in Sturgis, Michigan* (online at www fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutritions-facility) (accessed March 16, 2022).

[10] *Plant Behind Abbott Baby Formula Recall Was Unsanitary, FDA Finds*, CBS News (Mar. 23, 2022) (online at www.cbsnews.com/news/abbott-baby-formula-recall-fda-details/); Food and Drug Administration, *FDA Investigation of Cronobacter Infections: Powdered Infant Formula* (online at www fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022) (accessed Mar. 23, 2022).

To assist the Subcommittee in its review of this matter, we request that you provide the following information by April 7, 2022:

1. Why did FDA wait until February 17, 2022, to issue a warning to consumers not to use certain powdered infant formula produced at the Abbott Nutrition facility in Sturgis, Michigan?

2. What steps, if any, is FDA taking to ensure that it more quickly inspects facilities, and issues consumer warnings, after reports of foodborne illnesses linked to particular facilities?

We also request that you provide all documents and communications, from September 1, 2021, to the present, by April 7, 2022, related to the following topics:

1. Reports from Minnesota health authorities regarding *Cronobacter sakazakii* or *Salmonella* Newport infections traced back to the facility; and

2. FDA's steps to address the reported infections at the facility.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Subcommittee's request. Please contact Subcommittee staff at (202) 225-5051 if you have any questions about this request.

Sincerely,

Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable Michael Cloud, Ranking Member
Subcommittee on Economic and Consumer Policy

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term “including” shall be construed broadly to mean “including, but not limited to.”

5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.

7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term “individual” means all natural persons and all persons or entities acting on their behalf.

May 11, 2022

The Honorable Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy
Committee on Oversight and Reform
U.S. House of Representatives
Washington, DC 20515-6143

Dear Chairman Krishnamoorthi:

Thank you for your letter of March 24, 2022, regarding the Food and Drug Administration's (FDA or the Agency) investigation of consumer complaints and reports of infant illness related to products from Abbott Nutrition's facility in Sturgis, Michigan. FDA shares your deep concern about needing to protect vulnerable infants from foodborne illnesses. The Agency is investigating this matter diligently, in collaboration with federal, state, and local partners, and we are taking numerous steps to help ensure that parents and caregivers have access to safe and nutritious infant formula, which is the only source of nutrition for many newborns and infants. We would welcome the opportunity to brief you or your staff on this issue.

We would like to provide information to help explain the events leading up to FDA issuing a consumer advisory on this matter in February 2022. On September 20, 2021, FDA was made aware of a *Cronobacter* infection in an infant that consumed powdered infant formula (PIF) produced at the Sturgis, Michigan facility. FDA received additional reports of *Cronobacter* infections on November 17, 2021, December 1, 2021, and January 11, 2022. The Agency investigated each of the four consumer complaints, including analyzing product from consumers' homes when available. FDA also notified Abbott Nutrition after receiving each complaint.

As you know, the Centers for Disease Control and Prevention (CDC) receives reports on foodborne disease outbreaks from state, local, and territorial health departments. On average CDC receives two to four *Cronobacter* case reports annually. However, because *Cronobacter* is not a nationally notifiable condition, the four cases that came to our attention raised a concern. Further, the reported common exposure of each infant to PIF from one of the infant formula manufacturers serving the U.S. added to the Agency's concern. Given these factors, FDA decided to initiate a for-cause inspection at the Sturgis, Michigan, facility. While inspectional planning was initiated in late 2021 with an anticipated inspection date in early January 2022, the inspection did not commence until January 31, 2022, due to COVID-19 positive employees at the facility.

Over the course of the onsite inspection initiated in January 2022, the FDA inspection team observed significant operational deficiencies in the facility, which raised concerns regarding potential product contamination by *Cronobacter* or other pathogens. FDA investigators collected numerous product and environmental samples:

- Five environmental subsamples collected from the facility were positive for *Cronobacter sakazakii*; four were detected by FDA and one was detected through firm-initiated testing. The positive *Cronobacter sakazakii* environmental samples collected at the Sturgis, Michigan, facility have been analyzed using Whole Genome Sequencing, revealing five different strains of *Cronobacter sakazakii*.
- Product samples collected by FDA at the facility were analyzed for *Cronobacter* by FDA and were found negative.

As soon as the Agency received these positive sampling results in February 2022, we began conversations with the firm about issuing a voluntary recall. On February 17, 2022, we issued the public communication advising consumers not to use the affected products.

More information on our findings from the inspection initiated in January 2022, as well as FDA inspections conducted in September 2019 and September 2021, are available in the FDA Form 483s, available on online.[1] The inspectional observations in these Form 483s do not constitute final FDA determinations of whether any condition was or is in violation of the Federal Food, Drug, and Cosmetic Act or any of its implementing regulations. The Agency is currently evaluating the 2022 inspectional findings in determining the appropriate next steps, including any regulatory actions. This remains an open investigation with many moving parts.

We take seriously our duty to prevent, if possible, and respond to foodborne illnesses. Once we complete the active investigation and response activities, we will conduct an evaluation of the Agency's response to this incident and determine whether additional steps could be taken to ensure the maximum effectiveness of Agency programs and policies related to infant formula and special medical food complaints, illnesses, and recalls.

More broadly, and in the spirit of continuous improvement, we issued a Foodborne Outbreak Response Improvement Plan (FORIP) in December 2021, which will guide our efforts to enhance the speed, effectiveness, coordination, and communication of outbreak investigations. One goal outlined in the FORIP is the development of performance measures across FDA's foods program to better evaluate the timeliness and effectiveness of outbreak and regulatory investigation activities.

[1] *https://www.fda.gov/about-fda/office-regulatory-affairs/ora-foia-electronic-reading-room*

We appreciate your interest in this important issue and would be happy to discuss this issue further should you or your staff have any questions.

Sincerely,

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

cc: The Honorable Michael Cloud, Ranking Member
Subcommittee on Economic and Consumer Policy

United States Senate
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510–6300

April 11, 2022

The Honorable Robert M. Califf
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

I am deeply concerned about a new report into longstanding, significant delays and dysfunction across food safety efforts at the U.S. Food and Drug Administration (FDA). Americans rely on the FDA to ensure the food they are eating and feeding their families is safe. The FDA's failure over decades to regulate and enforce food safety standards, on issues ranging from bacteria in vegetables to arsenic in baby food, has put the health of Americans at risk. I am calling on you to make these issues a priority and take immediate action to ensure the FDA is doing all it can to fulfill all aspects of its mission to protect the health and safety of the American people.

According a recent media report based on over 50 interviews, the FDA's food safety efforts have received little attention within the agency and have been beset by delays and management challenges for years.[1] Despite overseeing nearly 80 percent of the American food supply, the FDA's predominant focus, the investigation found, has been on drugs and devices, while food safety issues have not been prioritized by senior leadership. Over the last decade, the food safety program has languished with delays across inspections and the development and issuance of safety standards. As one former acting FDA Commissioner put it, the food program is "on the back burner" at the agency. Other officials described the program as "impossible," "broken," "byzantine," and "a joke."

This report highlighted several delays in regulatory action that have endangered the public health. Over a decade after the Food Safety Modernization Act was implemented, the FDA has yet to issue safety standards required by the law, and hundreds of people have been sickened due to foodborne illness. Despite recognition within the agency of the danger of toxic elements in baby food, the FDA has not imposed strict safety standards, even as report after report has identified unacceptably high levels of lead, arsenic, mercury, cadmium, and other toxins in baby food. The agency has not even finalized long-term voluntary reduction targets for sodium in food, despite a recommendation to do so in 2010.

I am further concerned by the agency's failure to ensure timely inspections and recalls, which are critical for ensuring food is free of bacteria and other harmful contaminants. According to the

[1] https://www.politico.com/interactives/2022/fda-fails-regulate-food-health-safety-hazards/

report, the number of FDA food safety inspections has generally decreased over time. Inspections are also often delayed. For example, I have sought answers from both Abbott Nutrition and the FDA regarding potential bacterial contamination of Abbott's infant formula, which has been associated with multiple hospitalizations and deaths.[2] The FDA first received a report of these issues in September 2021, but failed to initiate an inspection of the manufacturing plant until January, before a voluntary recall in February.[3] The FDA has since found serious sanitation issues at the facility.[4] FDA inspections for facilities manufacturing other food products have also failed to identify the causes of bacteria in produce, and the agency has often waited months prior to issuing product recalls.[5]

These delays actively endanger the health and safety of the American people. Every year, approximately one in six Americans get sick and 3,000 die from foodborne diseases.[6] Exposure to toxic metals and chemicals like arsenic, lead, and cadmium – especially for children – have been linked with a higher risk of serious illness, lifelong impairment, and death.[7] The effects of poor nutrition are also significant. For example, a new analysis focused just on salt intake estimates the FDA's delay in finalizing sodium targets in food may result in over 260,000 deaths.[8]

You have the opportunity to address these longstanding issues and reform the way FDA handles these longstanding food safety and nutrition issues. During your confirmation hearing, you committed to me you would "hit the ground running" and prioritize consumer and patient protection issues.[9] I am calling on you to fulfill that promise and take immediate action to ensure the FDA's food safety efforts are robust, timely, and effective in keeping the American people healthy and safe.

In addition, I request the following information no later than April 25, 2022:

1. What steps are you taking or planning to take to improve the FDA's food safety efforts, including the timeliness and rigor of regulatory and enforcement activities?

2. The recent news report highlights significant, years-long delays in addressing water used to grow produce, toxic substances in baby food, and sodium levels in food. Has the FDA assessed the causes of these delays? If so, please provide the results or findings of any such assessment. If not, please explain why such assessments have not been conducted and if there are any plans to do so.

3. The report indicates that an organizational change made under the Trump Administration may have further hampered FDA's food safety efforts. What steps, if any, are you

[2] Letter from Senators Patty Murray and Bob Casey to Abbott Nutrition (Feb. 24, 2022); Briefing from FDA Staff (March 16, 2022).
[3] https://www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226
[4] https://www.fda.gov/media/157073/download
[5] https://www.politico.com/interactives/2022/fda-fails-regulate-food-health-safety-hazards/
[6] https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html
[7] https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food-a6772370847/
[8] https://www.ahajournals.org/doi/abs/10.1161/HYPERTENSIONAHA.121.18475
[9] https://www.help.senate.gov/imo/media/doc/Califf2.pdf

considering to ensure the FDA's organizational structure supports timely and effective decision-making on food-related issues?

4. For each year over the past ten years, how many:
    a. Food safety inspections has the FDA conducted? Please provide a breakdown by inspection type;
    b. Food and food packaging samples did the FDA test for toxic elements? Please provide a breakdown by food and packaging type. Please provide the results of any such tests for any products intended for infants or young children.

Thank you for your attention to this matter. Please direct any correspondence pertaining to this request to Yelena Tsilker at Yelena_Tsilker@help.senate.gov.

Sincerely,

Chair
U.S. Senator Committee on Health, Education,
Labor, and Pensions

cc: Senator Richard Burr
Ranking Member

May 24, 2022

The Honorable Patty Murray
Chair
Committee on Health, Education, Labor, and Pensions
United State Senate
Washington, D.C. 20510

Dear Chair Murray:

Thank you for your letter of April 11, 2022, requesting information related to the U.S. Food and Drug Administration's (FDA or the Agency) Foods Program. Your questions are important for all Americans, for there is no more quintessential governmental function than ensuring the safety of the products our Foods Program oversees.

Food safety and nutrition are critical priorities and central to our mission as an Agency. We take criticism seriously and acknowledge that, as we face challenges, we must strive for continuous improvement. Through our work, the Agency has been able to deliver on a number of major initiatives to advance food safety and nutrition policy over the past decade and has a bold vision to continue building upon these successes to further improve public health. However, we know there are areas where we must improve. For example, FDA and the Administration can and will do more to make our timelines as aggressive as possible, and we strive to accelerate our efforts to deliver the public health protection and oversight that American consumers expect from FDA.

First, while perhaps not the primary focus of the questions in your letter, we would like to address FDA's ongoing work to mitigate infant formula supply challenges in the U.S., an issue that is top of mind for the Agency and many Americans. FDA has and will continue to implement several important steps[1] to improve the supply of infant and specialty formula products in the U.S. Notably, on May 16, 2022, a consent decree of permanent injunction between the FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. Under the consent decree, Abbott has agreed to take corrective actions following an FDA inspection of its Sturgis, Michigan facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while ensuring that the company undertakes certain actions that would ensure safe powdered infant formula is produced at the facility. Additionally, also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Ensuring the availability of safe, sole-source nutrition products like infant formula is of the utmost importance to FDA. We

[1] *https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-improve-supply-infant-and-specialty-formula-products*

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

have been working tirelessly to address and alleviate supply issues and will continue doing everything within our authority to ensure the production of safe infant formula products.

As you know, the Foods Program has responsibility for a variety of areas, including ensuring the microbial and chemical safety of food, ensuring that consumers have access to information to make healthful food choices, and ensuring the safety of dietary supplements and cosmetics.

FDA continues the critical work needed to fully implement the FDA Food Safety Modernization Act (FSMA) through additional rulemakings, guidance development, training, inspections, and other implementation activities. We have published eight foundational final rules and more than 50 draft and final guidances to help transform our nation's food safety system to a prevention-oriented framework. Despite advancements in food safety over the past decade, rates of foodborne disease in the U.S have not changed significantly. To achieve our goal of bending the curve of foodborne illness, in 2020 we engaged with internal and external stakeholders to craft a vision for building on the progress made by FSMA while leveraging the use of new and emerging technologies and new approaches for a rapidly changing food system. The New Era of Smarter Food Safety (New Era) blueprint outlines FDA's bold approach for improving our programs to effectively respond to rapid changes and emerging issues in the global food safety system. New Era is an essential next step toward fully realizing the benefits of FSMA's prevention-oriented framework that translates into fewer foodborne illnesses.

A few recent accomplishments under the New Era initiative include:

- Improving the speed, effectiveness, coordination, and communication of outbreak investigations through the Foodborne Outbreak Response Improvement Plan (FORIP), developed with input from Federal and State public health officials, industry, and consumer foodborne outbreak experts;
- Detecting outbreaks and food safety issues earlier and with increased precision, including through our whole genome sequencing platform known as GenomeTrakr. Our work on GenomeTrakr has been a critically important paradigm shift in the control of foodborne illness;
- Enhancing the safety of leafy greens by improving strategies for prevention of Shiga-toxin producing *E. coli* (STEC), addressing knowledge gaps, and enhancing response activities by FDA and other entities under the Leafy Greens STEC Action Plan (LGAP). FDA continues to build on the original LGAP issued in 2020, making significant progress through collaborative action-oriented public-private partnerships;
- Piloting artificial intelligence/machine learning projects to improve our ability to identify imported food products of public health concern;
- Building stronger relationships with our state partners and trusted foreign partners to better coordinate our strategy and resources on targeting the highest-risk food safety issues through our mutual and systems recognition programs; and
- Working towards establishing frameworks for tech-enabled source-to-table food traceability that will build on the foundations established through the FSMA Food Traceability rulemaking, which should be completed by November 2022.

Our understanding of the role nutrition plays in the lives of everyday Americans has also progressed throughout the years, and, over the past decade, we advanced multiple nutrition policies to reduce the burden of diet-related chronic disease through improved nutrition. For example, our actions updating the Nutrition Facts Label with added sugars for the first time, removing industrially produced *trans* fats from our food system, implementing menu labeling so consumers can access not just calorie information but additional written nutrition information like sodium when ordering foods from chain restaurants, and reducing sodium in the diet have the potential to prevent hundreds of thousands of diet-related premature deaths and illnesses in the coming years. Indeed, the World Health Organization has told FDA that our work on *trans* fats and sodium is impactful in leading policies around the globe for healthier foods.

Finally, our Closer to Zero initiative identifies actions the Agency is taking to reduce exposure to toxic elements from foods eaten by babies and young children to as low as possible. We have prioritized babies and young children because their smaller body sizes and metabolism make them more vulnerable to the harmful effects of these contaminants. And we have seen our science-based approach to setting action levels already producing results in driving down contaminant levels and reducing exposure. From 2012 to 2018, we saw a 29 percent reduction of inorganic arsenic levels in infant rice cereal because of our efforts in developing an action level. This reduced exposure is predicted to decrease adverse health effects—such as lowering the median estimated lung and bladder cancer cases from consumption of inorganic arsenic in infant rice cereal during the first year of life by 60 percent (1.11 to 0.44 cases/million).[2] In April 2021, we issued the Closer to Zero action plan and followed that up with a public meeting in October. At the one-year anniversary mark, we issued a draft guidance on action levels for lead in juices commonly consumed by children and partnered with the U.S. Department of Agriculture on a second Closer to Zero public meeting (April 27). We also anticipate soon releasing a guidance document on lead in food for babies and young children, which is in the final stages of Administration clearance.

The Agency is proud of these initiatives and believes that all establish a firm foundation on which to build for future successes in ensuring the safety of food and helping Americans establish healthy eating patterns. As noted above, FDA can do better, and so we would welcome the opportunity to discuss both our successes and areas for improvement with you in greater detail and to partner with you and other Members of Congress on implementing solutions to improve our efforts.

Your specific requests are restated below, in bold type, followed by the Agency's response.

1. **What steps are you taking or planning to take to improve the FDA's food safety efforts, including the timeliness and rigor of regulatory and enforcement activities?**

   While we have had a number of significant successes in our Foods Program, there are improvements to be made in FDA's food safety efforts, and the Agency is committed to making them. We know that stakeholders deserve a higher level of transparency from the

[2] *https://www.fda.gov/media/96071/download*

Agency in terms of Foods Program priorities. For example, advocacy and industry stakeholders alike have communicated that they appreciate the transparency of the Closer to Zero plan, the clearly defined deliverables and timelines, and the commitment to an iterative scientific approach, which are laid out on our Closer to Zero webpage.[3] We are committed to delivering the public health protection and oversight that consumers expect from FDA, including by improving the timeliness and rigor of our regulatory and enforcement activities and regularly communicating Foods Program priorities, plans, and progress to stakeholders. However, there is no way around the simple fact that the program's current capacity and resources are overwhelmed by the sheer magnitude of the responsibilities and the ever-growing and evolving industries FDA regulates.

Staffing: FDA's Center for Food Safety and Applied Nutrition (CFSAN) is operating with essentially the same number of staff as it has for decades. But staffing is particularly worrisome in areas such as diet-related disease and long-term risks from chemical contaminants. CFSAN's Office of Nutrition and Food Labeling operates with staffing equal to the number of teachers in an average Seattle high school.[4] The Foods Program would benefit if it had the agile hiring authorities that FDA's medical product centers received in 2016 under 21st Century Cures. Scientific experts in the Foods Program are reviewing food product and packaging innovations that will have population-wide impacts, often with data that is more limited than the clinical trial data that is available to review similar innovations in medical products. This requires increasing scientific, technical, statistical, and other expertise that FDA faces fierce competition to recruit. Modern hiring and pay authorities would enable the Foods Program to recruit and hire talented scientific staff with agility and speed on par with the private sector. These hiring authorities would be transformative for the Foods Program – FDA would be able to bring on the talent it needs to address the increasingly complex and exciting innovation in key program areas. We appreciate your leadership in including the expansion of the Cures hiring authorities in the FDA Safety and Landmark Advancements Act.[5]

Resources: Unlike most FDA Centers that receive significant funding through user fees, 97 percent of CFSAN's budget comes from budget authority. This means CFSAN's funding is not directly tied to the level of work it has relative to the scope of its mission, in contrast to most FDA Centers, which receive user fees and thus can scale up as the volume of incoming work increases. We appreciate the increased funding FDA received in the Consolidated Appropriations Act, 2022 and view it as a strong down payment for many of our critical initiatives. The President's FY 2023 budget request looks to build on those investments and enable the Foods Program to improve health equity through nutrition and reducing exposure to harmful chemicals and toxins in food, while strengthening data-driven approaches to protecting consumers, allocating regulatory oversight resources based on risk, and improving FDA's capacity to quickly respond to ongoing and evolving public health challenges in support of the Agency's continued implementation of the New Era of Smarter Food Safety. While Congress invested additional resources for standing up FSMA, the rate of increased

[3] *https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods*
[4] *https://washingtonstatereportcard.ospi.k12.wa.us/ReportCard/ViewSchoolOrDistrict/101062*
[5] *https://www.help.senate.gov/chair/newsroom/press/senators-murray-burr-release-legislation-to-support-fda-programs-to-lower-costs-and-spur-innovation-*

investment in FDA's foods program has significantly lagged behind those made in FDA's Center for Drug Evaluation and Research (see enclosure).

Again, FDA welcomes an opportunity to discuss these needs with you and work with you and other Members of Congress to help build capacity as we work to improve the timeliness and rigor of our Foods Program regulatory and enforcement activities to deliver oversight of foods on behalf of consumers.

2. **The recent news report highlights significant, years-long delays in addressing water used to grow produce, toxic substances in baby food, and sodium levels in food. Has the FDA assessed the causes of these delays? If so, please provide the results or findings of any such assessment. If not, please explain why such assessments have not been conducted and if there are any plans to do so.**

First, FDA is taking steps to improve the timeliness of its food safety efforts. Although not formal evaluations, the Agency has identified several elements that, while not unique to these issues, influenced project timelines for the agricultural water proposed rule, setting levels for toxic elements in baby food, and sodium reduction targets.

As with any complex, scientific issue, these three projects required research, analysis of data, and, in certain cases, engagement with the scientific community to inform decision-making and adjustments when new science emerged. Further, FDA's regulations and guidances often require intra-governmental review processes to solicit feedback from various parts of the U.S. government. The feedback and insight of our government partners can help make our policies stronger and more comprehensive, but the reviews are outside of our control and often require significant time. Finally, but importantly, stakeholder input also is essential to ensure that policies we put into place are feasible to implement once established. If we do not take the time to make sure our policies can be enacted in real-world settings, then they will not be successful and the intended public health benefits will not be realized or unintended consequences could result.

For example, regarding our sodium reduction targets, there were a myriad of considerations (e.g., potential food safety issues, advancements in food technology, adaptation of consumers' palates) that required a thorough and thoughtful process. In particular, we did not take a "one size fits all" approach, but rather developed targets that are specifically tailored for 163 food categories based on their unique food safety and food technology considerations. In addition to packaged food targets, the sodium reduction guidance includes targets for restaurant foods, recognizing the need to reduce sodium broadly across the food supply in order for palates to adjust –an approach other countries are seeking to emulate.

3. **The report indicates that an organizational change made under the Trump Administration may have further hampered FDA's food safety efforts. What steps, if any, are you considering to ensure the FDA's organizational structure supports timely and effective decision-making on food-related issues?**

We are taking a close look at the structure of FDA's Foods Program and whether it currently is operating as efficiently and effectively as possible. We want to be sure to look carefully at what we can do to ensure the Foods Program is best positioned for the challenges and opportunities of the next decade. We are seeing a convergence of the science, data, supply chain, and regulatory issues facing both medical and food products. We will take great care to look closely about how we can optimize operations, the use of data, leverage FDA's scientific expertise, and make the right investments to have the strongest possible Foods Program.

4. For each year over the past ten years, how many:

a. Food safety inspections has the FDA conducted? Please provide a breakdown by inspection type;

The table below shows the number of human food inspections conducted by FDA and its State Partners (performing inspections for FDA under FDA contract) during fiscal years (FY) 2011 through 2021. These inspections cover all Food Safety program areas, including but not limited to, Preventive Controls, Current Good Manufacturing Practices, Foreign Supplier Verification Programs, Dietary Supplements and Seafood. The "Inspection Type" is conveyed in these results as the operation type (i.e. domestic inspections, foreign inspections, FDA-conducted inspections, and inspections conducted by states).

Notably, FDA not only conducts inspections, but also performs other oversight activities related to Food Safety, including investigations and remote record(s) evaluations as part of its Food Safety Program.

Table 1: Human Food Inspection Counts by Fiscal Year

Operation Type	Conducted by/Fiscal Year	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Sum:
Domestic Food Inspection counts	FDA	10,517	10,086	7,658	7,133	7,334	7,933	8,484	8,629	7,254	3,941	4,657	**83,626**
Foreign Food Inspection counts	FDA	999	1,347	1,403	1,339	1,357	1,269	1,548	1,638	1,747	641	79	**13,367**
	FDA	**11,516**	**11,433**	**9,061**	**8,472**	**8,691**	**9,202**	**10,032**	**10,267**	**9,001**	**4,582**	**4,736**	**96,993**
Domestic Food Inspection counts	States	9,765	9,306	9,355	9,667	9,277	8,952	8,460	8,073	7,485	5,476	5,940	**91,756**

	States	**9,765**	**9,306**	**9,355**	**9,667**	**9,277**	**8,952**	**8,460**	**8,073**	**7,485**	**5,476**	**5,940**	**91,756**
Total Inspection Count	**Sum:**	**21,281**	**20,739**	**18,416**	**18,139**	**17,968**	**18,154**	**18,492**	**18,340**	**16,486**	**10,058**	**10,676**	**188,749**

Source: Inspection counts pulled from Field Food Program Activity Data (PAD) from FY 2013 – FY 2023 Justification of Estimates for Appropriations Committees.

b. Food and food packaging samples did the FDA test for toxic elements? Please provide a breakdown by food and packaging type. Please provide the results of any such tests for any products intended for infants or young children

Table 2 below shows the total number of food product samples collected by food type and FY2011-2022 for toxic element testing. FDA does not routinely conduct testing for toxic elements such as arsenic, cadmium, lead, and mercury in food packaging. Such toxic elements are not authorized for use in food packaging. Furthermore, present-day packaging materials are generally manufactured through a sequence of controlled synthetic steps, in which any environmental contamination from toxic elements are likely to be negligible and expected to be controlled through appropriate good manufacturing practices.

Table 2: Food Product Samples Collected for Toxic Elements testing by Food Type and Fiscal Year, FY2011-FY2021

Food Type by (Industry Code Description)/Fiscal Year	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	**Sum:**
Whole Grain/Milled Grain Prod/Starch	45	30	149	24	8	22	67	36	64	22	30	**497**
Bakery Prod/Dough/Mix/Icing	163	122	79	22	59	48	59	29	44	27	46	**698**
Macaroni/Noodle Prod	7	6	4	7	24	4	23	6	25	16	9	**131**
Cereal Prep/Breakfast Food	15	5	3	6	3	9	11	20	12	9	7	**100**
Snack Food Item	30	18	16	9	20	12	12	8	11	14	8	**158**
Milk/Butter/Dried Milk Prod	13	5	20	296	72	236	240	154	68	15	17	**1136**
Cheese/Cheese Prod								1			1	**2**
Ice Cream Prod		1	1						1			**3**
Filled Milk/Imit Milk Prod	9		1	2		6	1	13	6	1		**39**
Egg/Egg Prod	26	13	5	4	13	8	11	11	11	5	3	**110**
Fishery/Seafood Prod	364	137	179	148	177	73	92	3	1	3	2	**1179**

Meat, Meat Products and Poultry				7	33	54	48	39	38	11	1	**231**
Vegetable Protein Prod						1	2	1	1			**5**
*Fruit/Fruit Prod	244	604	134	253	355	297	367	284	293	184	143	**3158**
*Fruit/Fruit Prod	71	273	78	202	227	203	436	207	187	151	122	**2157**
*Fruit/Fruit Prod	10	40	12	20	24	23	24	34	30	28	12	**257**
Nuts/Edible Seed	11	3	7	10	10	12	16	40	24	24	80	**237**
*Vegetables/Vegetable Products	17	14	32	76	101	146	177	86	95	65	57	**866**
*Vegetables/Vegetable Products	31	29	51	116	177	134	143	132	88	85	124	**1110**
Vegetable Oils		9		7		1		2	3	5	3	**30**
Dressing/Condiment	11	12	21	13	25	41	25	28	32	14	14	**236**
Spices, Flavors And Salts	64	56	88	106	90	143	172	224	208	145	79	**1375**
Soft Drink/Water	51	33	35	15	16	55	67	36	52	23	25	**408**
Beverage Bases/Conc/Nectar	6	21	11	3	1	8	11	18	20	8	1	**108**
Coffee/Tea	17	7	5	32	43	4	26	11	9	7	20	**181**
Candy w/o Choc/Special/Chew Gum	381	137	150	111	111	99	93	76	93	86	57	**1394**
Choc/Cocoa Prod	110	17	54	39	60	74	69	36	68	41	26	**594**
Gelatin/Rennet/Pudding Mix/Pie Filling	2	8	13	4	10	5	9	3	9	4	2	**69**
Food Sweeteners (Nutritive)	17	63	109	145	46	105	134	80	83	20	19	**821**
Mult Food Dinner/Grav/Sauce/Special	5	7	24	15	19	6	14	5	19	31	12	**157**
Soup	5			1		1				1	2	**10**
Baby Food Prod	7	32	56	7	3	15	20	225	108	32	68	**573**
Dietary Conv Food/Meal Replacements	11	14	16	4	8	3	5	8	2		9	**80**
EDIBLE INSECTS AND INSECT-DERIVED FOODS									1		3	**4**
Food Additives (Human Use)	13			1	1	2	1		1		1	**20**
Food Additives (Human Use)	5	1					1					**7**
Color Additive Food/Drug/Cosmetic	1		9	2	9	2	2		1	1	3	**30**
Miscellaneous Food Related Items	1	1						2				**4**
Vit/Min/Prot/Unconv Diet(Human/Animal)	181	111	132	29	50	63	75	33	50	30	60	**814**
Sum:	**1944**	**1829**	**1494**	**1736**	**1795**	**1915**	**2453**	**1891**	**1758**	**1108**	**1066**	**18989**

*Some food types have multiple categories for similar food type groups

c. Please provide the results of any such tests for any products intended for infants or young children:

Table 3 (below) shows a breakdown of lab sample classifications (results) for toxic elements analysis/testing performed on the 573 Baby Food Product samples in Table 2 above.

Of those 573 Baby Food Product samples shown in Table 2 above, Table 3 shows 736 analyses/tests for toxic elements were performed using these products. Multiple analyses/tests may have been performed on a single product/sample collected. Definitions for FDA Lab Classifications are below the Baby Food Product testing/analysis count table cited here.

Table 3: *Baby Food Product toxic element testing/analysis count by Lab Classification and Fiscal Year, FY2011-FY2021

Lab Classification/Fiscal Year	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Sum:
In Compliance	4	12	7	6	3	14	17	154	94	29	54	**394**
Regulatory Action Not Established/Defined	3	25	48	1		3	5	166	37	4	15	**307**
Adverse Findings		2						13				**15**
No Classification Required		2	1					1			16	**20**
Sample Shipping and Collection Problems												**0**
Sum	**7**	**41**	**56**	**7**	**3**	**17**	**22**	**334**	**131**	**33**	**85**	**736**

This table displays product sample analysis/testing by count for products categorized by FDA as "Baby Food Product"
*Multiple analyses/tests may be performed on a single product/sample collected. Testing/analysis counts are not always a direct count/correlation to or of a single product/sample collected.
**Lab Class is assigned by the analyzing laboratory according to ORA Laboratory Manual Volume III Section 3 8.E. Sample Classifications. Lab classifications can be directed through specific directions in the sampling plan, or in consultation with the Center. Lab classifications do not always reflect additional technical and policy review necessary and are not the final indicator of Agency policy or outcome.

Food Products Lab Classification Summary:

1. **Lab Class 1 (In Compliance):** The sample meets established standards (CFR, USP, etc.) or policy guides in the absence of standards and no violation appears present.
2. **Lab Class 2 (Regulatory Action Not Established/Defined)**: Analytical results do not inherently establish a violation, but results may be referred for additional review. This referral can result in additional activities, such as investigation, laboratory analysis, sample characterization such as Whole Genome Sequencing (WGS), or policy review by other parts of the Agency, such as the Center, before determining whether and what follow-up is appropriate. For example, detection of Listeria species other than Listeria monocytogenes or quantifiable contaminants where policy remains unsettled.
3. **Lab Class 3 (Adverse Findings)**: The sample fails to meet established standards and policy guides; or the results, in the absence of standards and guides, are of a level or significance to support a recommendation for regulatory action. For example, listeria *monocytogenes* environmental samples are lab class 3, but require further evaluation before regulatory action can be supported.
4. **Lab Class 4 (No Classification Needed)**: The sample is not classified because of the type of examination or reason for analysis makes classification meaningless. Examples include survey samples where one sample consists of multiple products or where there is no documentation to support regulatory action.
5. **Lab Class 5 (Sample Shipping and Collection Problems)**: The sample is rendered unusable for analysis.

In addition to the regulatory sampling noted above, FDA collects surveillance and research samples for food. Notably, the FDA Total Diet Study (TDS) monitors levels of contaminants (e.g., cadmium and lead) and nutrients (e.g., calcium and iron) in foods commonly eaten by people in the U.S. The ongoing nature of the TDS enables us to track trends in the average U.S. diet. The foods are bought at retail outlets throughout the U.S., prepared as consumed, and analyzed for elements both toxic and nutrient. We make these data publicly available, and the results from 1991 to 2017 can be found on our website.[6] Results from 2018 to 2020 will be posted soon.

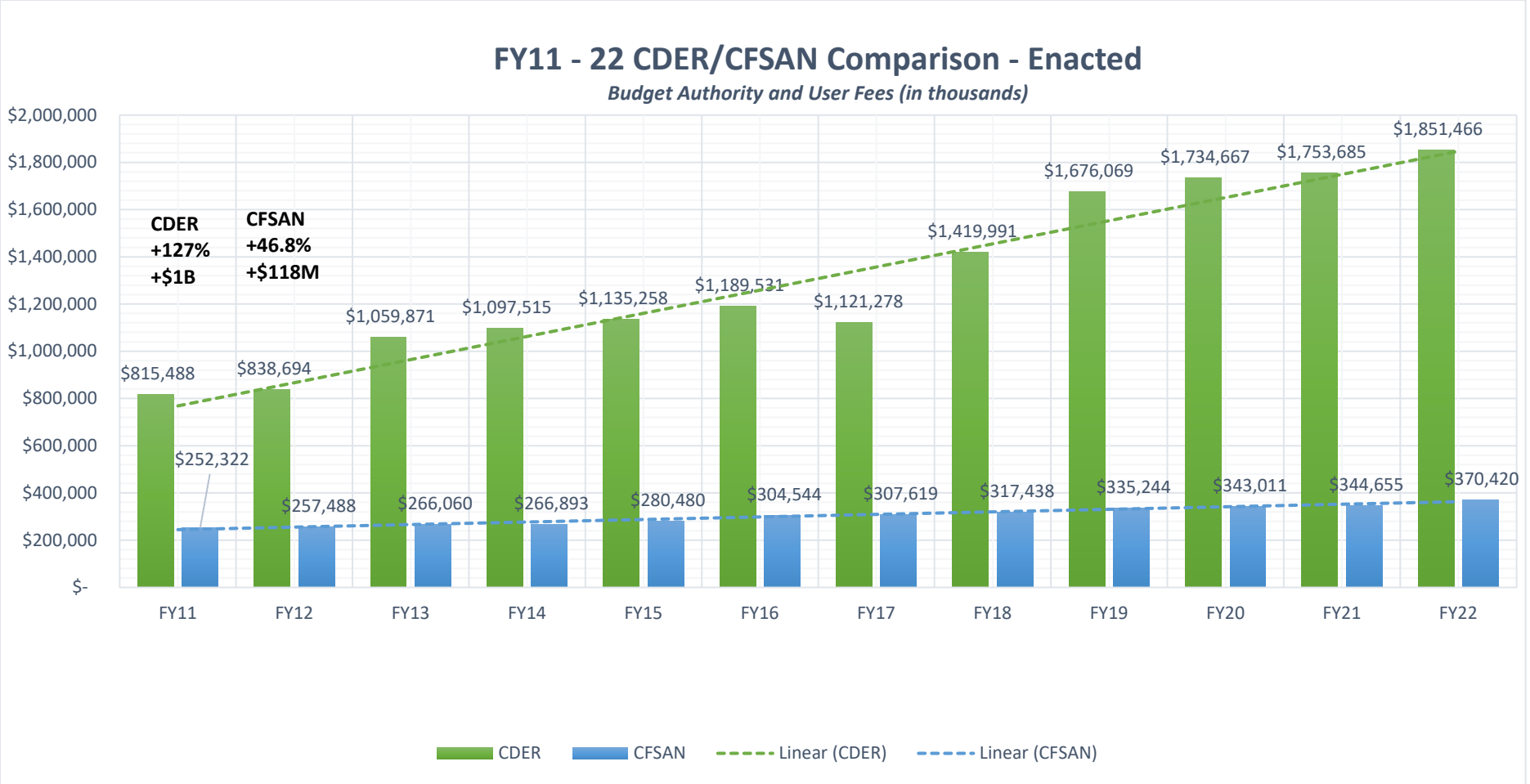
Thank you again for your continued interest in this important matter. The work of the Foods Program is critical to FDA's mission, and we are committed to our shared interest of advancing food safety and nutrition. We welcome the opportunity to discuss these areas with you and how we can continue to make improvements.

Sincerely,

Kimberlee Trzeciak
Associate Commissioner for
Legislative Affairs

[6] *https://www.fda.gov/food/total-diet-study/analytical-results-total-diet-study*

Enclosure



Addendum: Comparison of CFSAN vs CDER funding FY11 – FY22

From: Ganter, Jack
To: Legislation
Subject: [EXTERNAL] baby formula shortage
Date: Thursday, May 5, 2022 9:43:20 PM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
image006.png

Good afternoon,

We have had several constituents reach out to us about the recent baby food shortage. My boss would like to help in **ANY** way possible. Please let us know ASAP how our office can be beneficial.

'It's absolutely heartbreaking': Jacksonville-area parents face worsening baby formula shortage

Happy to chat over the phone about this.

Thanks and look forward to hearing from you soon.

Jack Ganter
Health Legislative Assistant
2432 Rayburn HOB | 202-225-5831

Congressman BUDDY CARTER
Georgia's First District

From: Moxley, Shera
To: Ganter, Jack
Cc: Goitom, Mahlet
Subject: RE: [EXTERNAL] baby formula shortage
Date: Monday, May 9, 2022 4:01:00 PM
Attachments: image037.png
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Hi Jack,

Good to chat with you earlier today. Here are the materials I mentioned I'd send you:

1. Here's our webpage tracking the Abbott infant formula recall: https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022. Previous updates are all the way at the bottom, from the initial investigation notice on February 17, 2022, and the voluntary recall notice on February 20, through additional updates throughout February and March, including our recent update (in the blue box) where we don't object to Abbott releasing certain specialty and metabolic formulas on a case-by-case basis. This section includes contact information at Abbott for parents and caregivers to request products, and also the risk-benefit disclaimer I mentioned. Additional updates will be posted at this same location.

2. Links to the "483s," inspection observations from inspections at Abbott's Sturgis, Michigan, facility on the following dates:
    - September 16-24, 2019: https://www.fda.gov/media/157319/download
    - September 20-24, 2021: https://www.fda.gov/media/157318/download, https://www.fda.gov/media/157317/download (amended)
    - January 31 – March 18, 2022: https://www.fda.gov/media/157708/download

3. FDA's FY 2023 A-19, "Preventing Food Shortages, Including Infant Formula and Certain Medical Foods": https://www.fda.gov/media/157194/download (page 6).

Additionally, I'll keep you updated as FDA has new information to share on the Abbott infant formula recall and related shortage issue. As I mentioned, we're conducting an internal assessment of the Abbott case, including the supply chain impacts, and we may identify additional ways to strengthen FDA's oversight of the infant formula and medical foods industry beyond what's proposed in the A-19 about supply chain/shortages.

Thanks, again, for your interest in helping resolve the supply chain issues and your support for strengthening FDA's authorities in the infant formula program.

Sincerely,
Shera Moxley

Shera A. Moxley, PhD
Congressional Affairs Specialist

Office of Legislation
Office of Policy, Legislation, and International Affairs
U.S. Food and Drug Administration
Tel: 240.402.1594
Mobile: (b) (6)
shera.moxley@fda.hhs.gov

From: Ganter, Jack <Jack.Ganter@mail.house.gov>
Sent: Monday, May 9, 2022 9:41 AM
To: Moxley, Shera <Shera.Moxley@fda.hhs.gov>
Subject: Re: [EXTERNAL] baby formula shortage

Yes, you can reach me at (b) (6).

Look forward to chatting soon!

Jack Ganter
Health Legislative Assistant

2432 Rayburn HOB | 202-225-5831

From: "Moxley, Shera" <Shera.Moxley@fda.hhs.gov>
Date: Monday, May 9, 2022 at 9:36 AM
To: "Ganter, Jack" <Jack.Ganter@mail.house.gov>
Subject: RE: [EXTERNAL] baby formula shortage

Hi Jack,

If 1:30 today is still free for you, let me give you a call then. Does the 202-225-5831 number in your signature work best?

Shera

From: Ganter, Jack <Jack.Ganter@mail.house.gov>
Sent: Saturday, May 7, 2022 2:13 PM
To: Moxley, Shera <Shera.Moxley@fda.hhs.gov>
Subject: Re: [EXTERNAL] baby formula shortage

Hey Shera – appreciate the quick response. Sorry I wasn't able to get to this until today.

I am free to chat this weekend and can talk on Monday as well. Below are some times that works for me on Monday:
9am-10am
11am
1:30pm
3pm.

Thanks and look forward to hearing from you soon.

Jack Ganter
Health Legislative Assistant
2432 Rayburn HOB | 202-225-5831

From: "Moxley, Shera" <Shera.Moxley@fda.hhs.gov>
Date: Friday, May 6, 2022 at 12:42 PM
To: "Ganter, Jack" <Jack.Ganter@mail.house.gov>
Subject: RE: [EXTERNAL] baby formula shortage

Hi Jack,

Thanks very much for your email about infant formula shortages.

I'd be happy to chat with you this afternoon to understand more specifically how Rep. Carter is interested in helping.

I'm available this afternoon between 1:00-1:30, 2:30-3:00, and 4:00-5:00, at (b) (6) .

I look forward to speaking with you.

Sincerely,
Shera Moxley

Shera A. Moxley, PhD
Congressional Affairs Specialist

Office of Legislation
Office of Policy, Legislation, and International Affairs
U.S. Food and Drug Administration
Tel: 240.402.1594
Mobile: (b) (6)
shera.moxley@fda.hhs.gov

From: Ganter, Jack <Jack.Ganter@mail.house.gov>
Sent: Thursday, May 5, 2022 9:43 PM
To: Legislation <Legislation@fda.hhs.gov>
Subject: [EXTERNAL] baby formula shortage

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'It's absolutely heartbreaking': Jacksonville-area parents face worsening baby formula shortage

Happy to chat over the phone about this.

Thanks and look forward to hearing from you soon.

Jack Ganter
Health Legislative Assistant
2432 Rayburn HOB | 202-225-5831

REPLY TO:

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United States Senate

CHARLES E GRASSLEY
PRES DENT PRO TEMPORE EMER TUS
WASHINGTON DC 20510 1501

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☐ 210 WATERLOO BUILDING
531 COMMERCIAL STREET
WATERLOO, IA 50701–5497
(319) 232–6657

☐ 201 WEST 2ND STREET
SUITE 720
DAVENPORT, IA 52801–1817
(563) 322–4331

☐ 307 FEDERAL BUILDING
8 SOUTH 6TH STREET
COUNCIL BLUFFS, IA 51501–4204
(712) 322–7103

May10, 2022

The Honorable Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Califf,

I am writing with concern about the current shortage of infant formula in Iowa, and nationwide. Access to a steadfast, nutritional food supply is critical for all Americans, especially children. As supply chain shortages continue to impact families, I ask that the FDA prioritize our nation's critical need for infant formula and do what the agency can to ease the shortages.

As you likely know, supplies of infant formula have significantly decreased over the last few months. At the end of April, out-of-stock formula percentage increased to 40%, leading many retail stores to limit consumer purchases of formula. Further, in six states including Iowa, more than half of all baby formula was completely sold out during the week of April 24th. While the most common use of formula is feeding infants, many children and adults who are fed through feeding tubes also rely on formula for all of their nutrition. This is a staple that cannot be substituted.

With inflation at a 40 year high, Americans are already experiencing strain and adversity when they make trips to their local grocery stores. Many families in Iowa and across the U.S. rely on formula, but current supply chain issues and high prices are forcing low and middle income Americans to stretch their dollars and their formula even further. Shortages are also causing families to turn to unsafe methods of feeding their babies, such as making homemade formula or adding extra water to a bottle to stretch their supply. These makeshift methods of making up for a lack of supply in stores can be deadly.

I recognize the impact the COVID-19 pandemic and decreased workforce capacity has had on our supply chains. However, it is imperative that Americans have access to food that infants and others need to survive. It is the utmost importance to our families across the country that a

reliable supply of formula is reestablished immediately.

Therefore, I ask that you respond to the below questions by May 24, 2022. Please number your responses.

1.While there have been ongoing shortages for more than six months, the recent recall of Similac formulas produced by Abbott Laboratories and subsequent shutdown of the facility in Sturgis, Michigan have exacerbated the shortages. What steps has the FDA taken to allow the company to quickly resume the safe production of formula at this facility?

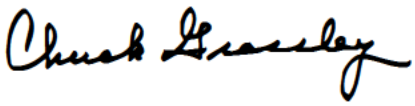
2.What are the plans to mitigate the effects of the recent recall of formula on the supply of formula across all brands?

3.What actions is the FDA taking to alleviate shortages and when does the FDA estimate that Americans will once again have reliable access to formula?

4.Does FDA have any plans to modify oversight or investigation procedures to ensure that in the future, families have consistent access to safe formula?

Should you have any questions please reach out to my office. On behalf of all Iowa families, I ask for a detailed, prompt, and thorough response.

Sincerely,



Charles Grassley
United States Senator

Congress of the United States

Washington, DC 20510

May 11, 2022

The Honorable Joseph R. Biden, Jr.
President of the United States
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

The Honorable Robert M. Califf, M.D., MACC
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

President Biden and Dr. Califf:

We write to you about concerns over the nationwide shortage of baby formula and your failure to meaningfully address this ongoing crisis. Parents are understandably frustrated and scared by this shortage. In fact, the formula shortage has reached crisis levels in recent weeks. The share of baby formula "out of stock across the U.S. hit 40 percent on April 24" and a "total of 26 states have out of stock rates of 40 to 50 percent."[1] Notably, CVS, Walgreens, and Target are among the stores putting limits on how much formula customers can buy at one time.[2] Additionally, there is concern over how this may impact parents participating in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), who rely on the program's supply of baby formula for their infant's nutritional needs.

According to Datasembly, baby formula shortages were at 23 percent in January 2022 "and have continued to worsen, showing [out of stock] levels now at 31% as of April 2022."[3] Further, Ben Reich, the CEO of Datasembly, said a combination of "inflation, supply chain shortages, and product recalls have brought an unprecedented amount of volatility for baby formula" and that he expects "to continue to see the baby formula category being dramatically

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[1] Rob Wile, *40 percent of America's baby formula supplies are out of stock*, NBC News (May 9, 2022), *available at* https://www.cnbc.com/2022/05/09/40-percent-of-americas-baby-formula-supplies-are-out-of-stock html

[2] Rachel Paula Abrahamson and Elise Sole, *Everything you need to know about the baby formula shortage*, Today (Feb. 9, 2022), *available at* https://www.today.com/parents/parents/everything-need-know-baby-formula-shortage-rcna15613?icid=canonical_related

[3] Business Wire, *Datasembly Data Reveals 31% Out-Of-Stock Rate in April 2022 for Baby Formula; Up 11% Compared to November 2021*, (Apr. 13, 2022), *available at* https://www.businesswire.com/news/home/20220413005974/en/Datasembly%E2%80%99s-Data-Reveals-31-Out-of-Stock-Rate-in-April-2022-for-Baby-Formula-Up-11-Compared-to-November-2021

affected by these conditions."[4] Mr. Reich warns that baby formula "will continue to demonstrate higher than average out-of-stock levels."[5]

Parents across the country are struggling to keep up with this nationwide shortage of baby formula. This problem worsened in February 2022 when, Abbott Nutrition, a manufacturer of infant formula, voluntarily recalled formula produced in its Sturgis, Michigan facility following reports of infant hospitalizations and death. The facility was subsequently shut down pending an investigation by the FDA and enhanced testing. Since then, a link has not been established between the formula produced at the facility and the sickened infants.

On April 29, 2022, the FDA announced that it did not object to Abbott Nutrition releasing specialty and metabolic formulas produced at the Sturgis facility on a case-by-case basis. Yet, the FDA has still not cleared the facility to resume the vast majority of its infant formula production. The prolonged shutdown of the Sturgis facility without any public backup plan by the administration has greatly exacerbated the current shortage.

Baby formula shortages are an urgent problem that must be addressed immediately. This new problem is compounded by the historic inflation caused by the Biden administration that is already burdening families. The office of the U.S. Surgeon General states that families typically spend $1,200 to $1,500 on infant formula in the first year.[6]

Just yesterday, the FDA announced a number of steps it will take in an attempt to "improve supply of infant and specialty formula products."[7] However, this announcement comes far too late, as parents struggle to find formula for their babies. House Republicans call on the administration to do more to help parents across this country. This issue is a matter of life and death, and it is time this administration treats it with the appropriate urgency it deserves. Accordingly, to assist us in our oversight, please provide the following by May 18, 2022:

1. Please explain the meaning of FDA's April 29, 2022, update, and if FDA expects its non-objection to help mitigate the supply shortage? If so, how is it expected to mitigate the shortage? Please explain how long the additional testing is expected to take and what the timeline is for reopening Abbott's Sturgis, Michigan facility.

2. With respect to the steps FDA recently announced, please answer the following:

    a. How will these steps meaningfully increase supply?

    b. When does the agency expect to see a supply increase, particularly in states experiencing significant shortages?

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[4] *Id*.
[5] *Id*.
[6] Office of Surgeon General, *Breastfeeding: Surgeon General's Call to Action Fact Sheet*, *available at* https://www.hhs.gov/surgeongeneral/reports-and-publications/breastfeeding/factsheet/index html
[7] FDA, *FDA Takes Important Steps to Improve Supply of Infant and Specialty Formula Products*, (May 10, 2022), *available at* https://content.govdelivery.com/accounts/USFDA/bulletins/317391e

c. Please identify what and the number of specific "reviews" and "certificates" in the regulatory process you are "expediting" to increase supply.

d. Please explain how you will exercise discretion on "minor labeling issues" to increase supply?

e. Are there any additional steps the FDA is considering?

3. What is FDA's understanding of what is causing the shortage of infant formula?

4. How did FDA account for infant formula supply impacts from the recalls?

5. What action is FDA taking to track the shortage?

6. What action is FDA taking related to the resolution of any issues resulting in the temporary closure of the facility in Sturgis, MI?

7. What outreach has the administration performed to hospital pediatric units to determine if they have enough baby and specialty formula in reserve for emergency situations?

8. What data is available regarding whether non-infants who rely on specialty formula are having any adverse reactions to currently available formula?

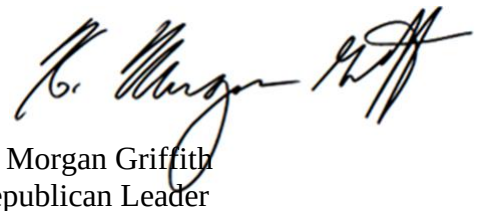
9. What formula production facilities are available beyond U.S. borders, and to what extent have these facilities been impacted by transit bottlenecks due to COVID lockdowns?

Please also provide a briefing for the Minority staff of the Energy and Commerce Committee after sending your written response. If you have any questions, please contact the Minority Committee staff at (202) 225-3641. Thank you for your attention to this request.

Sincerely,

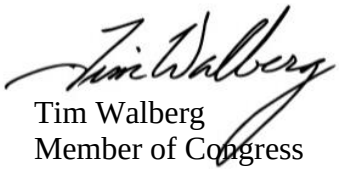
Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

Brett Guthrie
Republican Leader
Subcommittee on Health
Committee on Energy and Commerce

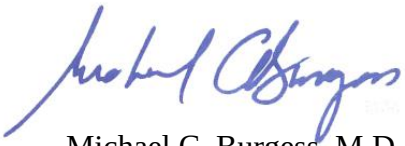


H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

Fred Upton
Member of Congress



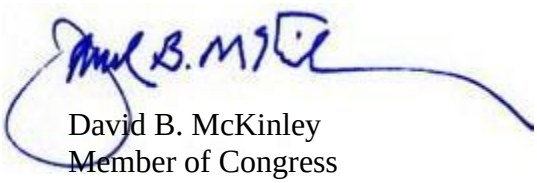
Tim Walberg
Member of Congress



Michael C. Burgess, M.D.
Member of Congress

Steve Scalise
Member of Congress

Robert E. Latta
Member of Congress

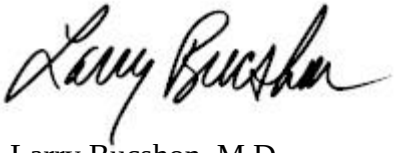


David B. McKinley
Member of Congress

Gus M. Bilirakis
Member of Congress

Bill Johnson
Member of Congress

Billy Long
Member of Congress



Larry Bucshon, M.D.
Member of Congress

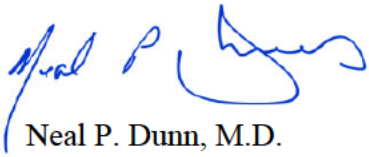
Markwayne Mullin
Member of Congress

Richard Hudson
Member of Congress

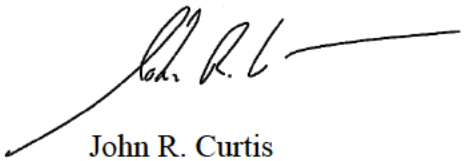
Earl L. “Buddy” Carter
Member of Congress

Jeff Duncan
Member of Congress

Gary J. Palmer
Member of Congress



Neal P. Dunn, M.D.
Member of Congress



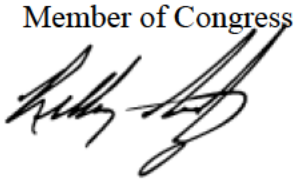
John R. Curtis
Member of Congress

Debbie Lesko
Member of Congress

Greg Pence
Member of Congress

Dan Crenshaw
Member of Congress

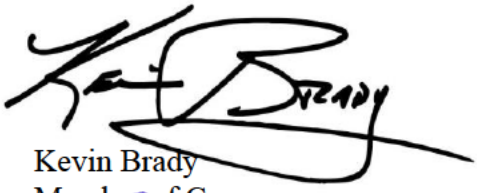
John Joyce, M.D.
Member of Congress



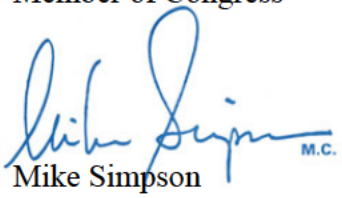
Kelly Armstrong
Member of Congress

Ken Calvert
Member of Congress

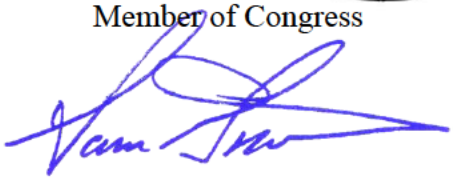
Frank D. Lucas
Member of Congress



Kevin Brady
Member of Congress



Mike Simpson
Member of Congress



Sam Graves
Member of Congress

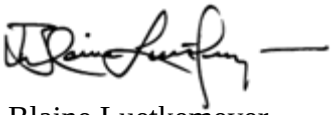
Darrell Issa
Member of Congress

Virginia Foxx
Member of Congress

Vern Buchanan
Member of Congress

Doug Lamborn
Member of Congress

Rob Wittman
Member of Congress



Blaine Luetkemeyer
Member of Congress

Tom McClintock
Member of Congress

Glenn “GT” Thompson
Member of Congress

Eric A. “Rick” Crawford
Member of Congress

Mo Brooks
Member of Congress

Bob Gibbs
Member of Congress

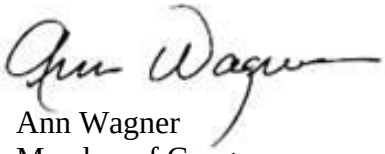
Bill Huizenga
Member of Congress

Steven M. Palazzo
Member of Congress

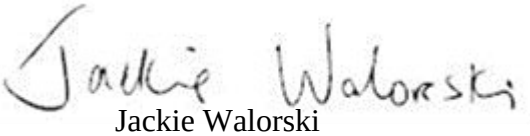
Austin Scott
Member of Congress

Andy Barr
Member of Congress

Doug LaMalfa
Member of Congress



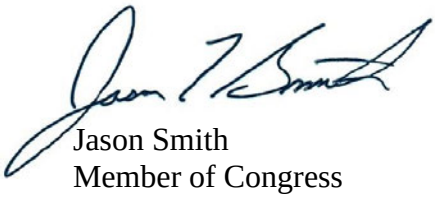
Ann Wagner
Member of Congress



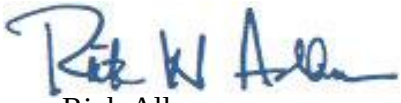
Jackie Walorski
Member of Congress

Brad R. Wenstrup, D.P.M
Member of Congress

Roger Williams
Member of Congress

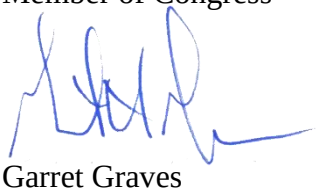


Jason Smith
Member of Congress



Rick Allen
Member of Congress

Tom Emmer
Member of Congress

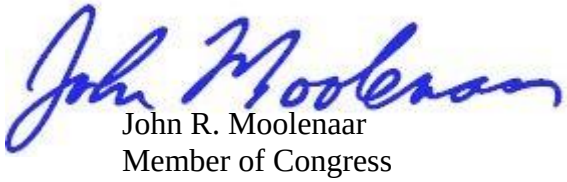


Garret Graves
Member of Congress

Glenn Grothman
Member of Congress

John Katko
Member of Congress

Barry Loudermilk
Member of Congress



John R. Moolenaar
Member of Congress

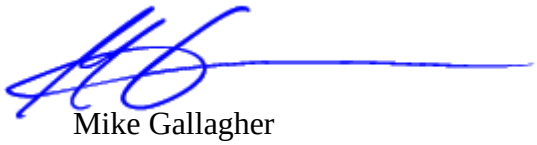
Dan Newhouse
Member of Congress

Elise Stefanik
Member of Congress

David G. Valadao
Member of Congress

Drew Ferguson
Member of Congress

Brian Fitzpatrick
Member of Congress



Mike Gallagher
Member of Congress

Clay Higgins
Member of Congress

John H. Rutherford
Member of Congress

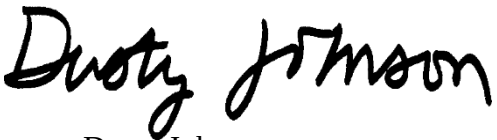
Ralph Norman
Member of Congress

Ben Cline
Member of Congress

Anthony Gonzalez
Member of Congress

Mark E. Green, M.D.
Member of Congress

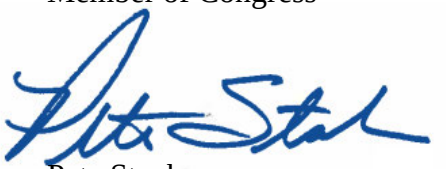
Michael Guest
Member of Congress



Dusty Johnson
Member of Congress

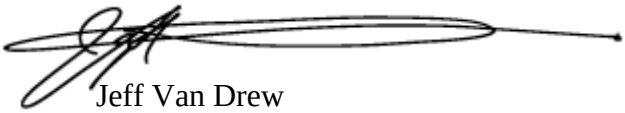
Guy Reschenthaler
Member of Congress

John Rose
Member of Congress

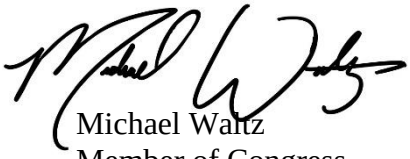


Pete Stauber
Member of Congress

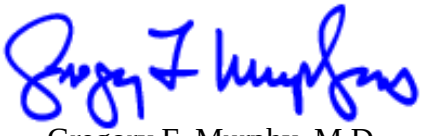
William R. Timmons, IV
Member of Congress



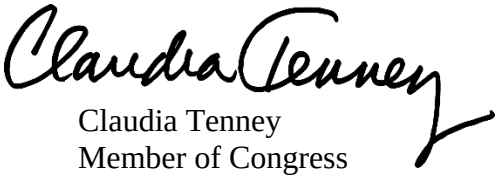
Jeff Van Drew
Member of Congress



Michael Waltz
Member of Congress



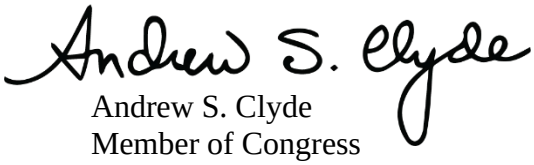
Gregory F. Murphy, M.D.
Member of Congress



Claudia Tenney
Member of Congress

Cliff Bentz
Member of Congress

Kat Cammack
Member of Congress



Andrew S. Clyde
Member of Congress

Michelle Fischbach
Member of Congress

Bob Good
Member of Congress

Diana Harshbarger
Member of Congress

Yvette Herrell
Member of Congress

Jake LaTurner
Member of Congress

Nancy Mace
Member of Congress

Tracey Mann
Member of Congress

Peter Meijer
Member of Congress

Mariannette J. Miller-Meeks, M.D.
Member of Congress

Blake Moore
Member of Congress

August Pfluger
Member of Congress

Maria Elvira Salazar
Member of Congress

Beth Van Duyne
Member of Congress

Carol D. Miller
Member of Congress

Daniel Webster
Member of Congress

Vicky Hartzler
Member of Congress

Andrew R. Garbarino
Member of Congress

Louie Gohmert
Member of Congress

Mike Garcia
Member of Congress

Jack Bergman
Member of Congress

Stephanie Bice
Member of Congress

Robert B. Aderholt
Member of Congress

Chris Stewart
Member of Congress

May 24, 2022

The Honorable Robert Aderholt
U.S. House of Representatives
Washington, DC 20515

Dear Representative Aderholt:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Rick Allen
U.S. House of Representatives
Washington, DC 20515

Dear Representative Allen:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Kelly Armstrong
U.S. House of Representatives
Washington, DC 20515

Dear Representative Armstrong:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Andy Barr
U.S. House of Representatives
Washington, DC 20515

Dear Representative Barr:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

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The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Cliff Bentz
U.S. House of Representatives
Washington, DC 20515

Dear Representative Bentz:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

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- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
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- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Jack Bergman
U.S. House of Representatives
Washington, DC 20515

Dear Representative Bergman:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Stephanie Bice
U.S. House of Representatives
Washington, DC 20515

Dear Representative Bice:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Gus Bilirakis
U.S. House of Representatives
Washington, DC 20515

Dear Representative Bilirakis:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

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We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

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Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Bill Johnson
U.S. House of Representatives
Washington, DC 20515

Dear Representative Johnson:

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The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Kevin Brady
U.S. House of Representatives
Washington, DC 20515

Dear Representative Brady:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

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Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Mo Brooks
U.S. House of Representatives
Washington, DC 20515

Dear Representative Brooks:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Vernon Buchanon
U.S. House of Representatives
Washington, DC 20515

Dear Representative Buchanon:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

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Update on Current Situation

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Larry Bucshon
U.S. House of Representatives
Washington, DC 20515

Dear Representative Bucshon:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Michael Burgess
U.S. House of Representatives
Washington, DC 20515

Dear Representative Burgess:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Ken Calvert
U.S. House of Representatives
Washington, DC 20515

Dear Representative Calvert:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

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The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

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Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Kat Cammack
U.S. House of Representatives
Washington, DC 20515

Dear Representative Cammack:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

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We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Buddy Carter
U.S. House of Representatives
Washington, DC 20515

Dear Representative Carter:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Ben Cline
U.S. House of Representatives
Washington, DC 20515

Dear Representative Cline:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

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We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

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Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Andrew Clyde
U.S. House of Representatives
Washington, DC 20515

Dear Representative Clyde:

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Rick Crawford
U.S. House of Representatives
Washington, DC 20515

Dear Representative Crawford:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

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The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Dan Crenshaw
U.S. House of Representatives
Washington, DC 20515

Dear Representative Crenshaw:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

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- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
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- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable John Curtis
U.S. House of Representatives
Washington, DC 20515

Dear Representative Curtis:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

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The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Jeff Duncan
U.S. House of Representatives
Washington, DC 20515

Dear Representative Duncan:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
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- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

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The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Neal Dunn
U.S. House of Representatives
Washington, DC 20515

Dear Representative Dunn:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Dusty Johnson
U.S. House of Representatives
Washington, DC 20515

Dear Representative Johnson:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Tom Emmer
U.S. House of Representatives
Washington, DC 20515

Dear Representative Emmer:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

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Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Drew Ferguson
U.S. House of Representatives
Washington, DC 20515

Dear Representative Ferguson:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Michelle Fischbach
U.S. House of Representatives
Washington, DC 20515

Dear Representative Fischbach:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

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What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Brian Fitzpatrick
U.S. House of Representatives
Washington, DC 20515

Dear Representative Fitzpatrick:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Virginia Foxx
U.S. House of Representatives
Washington, DC 20515

Dear Representative Foxx:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Michael Gallagher
U.S. House of Representatives
Washington, DC 20515

Dear Representative Gallagher:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Andrew Garbarino
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Washington, DC 20515

Dear Representative Garbarino:

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The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

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The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
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- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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Digitally signed by Kimberlee R. Trzeciak -S
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Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Mike Garcia
U.S. House of Representatives
Washington, DC 20515

Dear Representative Garcia:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Garret Graves
U.S. House of Representatives
Washington, DC 20515

Dear Representative Graves:

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The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

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In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Bob Gibbs
U.S. House of Representatives
Washington, DC 20515

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Louie Gohmert
U.S. House of Representatives
Washington, DC 20515

Dear Representative Gohmert:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
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In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Anthony Gonzalez
U.S. House of Representatives
Washington, DC 20515

Dear Representative Gonzalez:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

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Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

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- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Robert Good
U.S. House of Representatives
Washington, DC 20515

Dear Representative Good:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Mark Green
U.S. House of Representatives
Washington, DC 20515

Dear Representative Green:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable H. Morgan Griffith
Ranking Member
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
U.S. House of Representatives
Washington, DC 20515

Dear Ranking Member Griffith:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

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We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

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Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Glenn Grothman
U.S. House of Representatives
Washington, DC 20515

Dear Representative Grothman:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Michael Guest
U.S. House of Representatives
Washington, DC 20515

Dear Representative Guest:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Brett Guthrie
Ranking Member
Committee on Energy and Commerce
Subcommittee on Health
U.S. House of Representatives
Washington, DC 20515

Dear Ranking Member Guthrie:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

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Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Diana Harshbarger
U.S. House of Representatives
Washington, DC 20515

Dear Representative Harshbarger:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

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What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Vicky Hartzler
U.S. House of Representatives
Washington, DC 20515

Dear Representative Hartzler:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

U.S. Food & Drug Administration
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Silver Spring, MD 20993
www.fda.gov

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Yvette Herrell
U.S. House of Representatives
Washington, DC 20515

Dear Representative Herrell:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

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- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Clay Higgins
U.S. House of Representatives
Washington, DC 20515

Dear Representative Higgins:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Richard Hudson
U.S. House of Representatives
Washington, DC 20515

Dear Representative Hudson:

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The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

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- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
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Kimberlee Trzeciak
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May 24, 2022

The Honorable Bill Huizenga
U.S. House of Representatives
Washington, DC 20515

Dear Representative Huizenga:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Darrell Issa
U.S. House of Representatives
Washington, DC 20515

Dear Representative Issa:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

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Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable John Joyce
U.S. House of Representatives
Washington, DC 20515

Dear Representative Joyce:

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable John Katko
U.S. House of Representatives
Washington, DC 20515

Dear Representative Katko:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

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- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Doug LaMalfa
U.S. House of Representatives
Washington, DC 20515

Dear Representative LaMalfa:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

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Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

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- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Doug Lamborn
U.S. House of Representatives
Washington, DC 20515

Dear Representative Lamborn:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Robert Latta
U.S. House of Representatives
Washington, DC 20515

Dear Representative Latta:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Jake LaTurner
U.S. House of Representatives
Washington, DC 20515

Dear Representative LaTurner:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Debbie Lesko
U.S. House of Representatives
Washington, DC 20515

Dear Representative Lesko:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Billy Long
U.S. House of Representatives
Washington, DC 20515

Dear Representative Long:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

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Your letter raises questions that fall into four broad areas, which we address below.

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Barry Loudermilk
U.S. House of Representatives
Washington, DC 20515

Dear Representative Loudermilk:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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FDA Actions to Date

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

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The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Frank Lucas
U.S. House of Representatives
Washington, DC 20515

Dear Representative Lucas:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Blaine Luetkemeyer
U.S. House of Representatives
Washington, DC 20515

Dear Representative Luetkemeyer:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

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- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Nancy Mace
U.S. House of Representatives
Washington, DC 20515

Dear Representative Mace:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

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Stakeholder Outreach

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Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Tracey Mann
U.S. House of Representatives
Washington, DC 20515

Dear Representative Mann:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Tom McClintock
U.S. House of Representatives
Washington, DC 20515

Dear Representative McClintock:

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The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

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Stakeholder Outreach

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Kimberlee Trzeciak
Associate Commissioner
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May 24, 2022

The Honorable David McKinley
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Washington, DC 20515

Dear Representative McKinley:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Ranking Member Rodgers:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

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Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Peter Meijer
U.S. House of Representatives
Washington, DC 20515

Dear Representative Meijer:

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Mariannette Miller-Meeks
U.S. House of Representatives
Washington, DC 20515

Dear Representative Miller-Meeks:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

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- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Carol Miller
U.S. House of Representatives
Washington, DC 20515

Dear Representative Miller:

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The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

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Update on Current Situation

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- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable John Moolenaar
U.S. House of Representatives
Washington, DC 20515

Dear Representative Moolenaar:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Blake Moore
U.S. House of Representatives
Washington, DC 20515

Dear Representative Moore:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Markwayne Mullin
U.S. House of Representatives
Washington, DC 20515

Dear Representative Mullin:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

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We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

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Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Gregory Murphy
U.S. House of Representatives
Washington, DC 20515

Dear Representative Murphy:

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The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

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Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
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- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

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Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Dan Newhouse
U.S. House of Representatives
Washington, DC 20515

Dear Representative Newhouse:

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Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Ralph Norman
U.S. House of Representatives
Washington, DC 20515

Dear Representative Norman:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

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Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Steven Palazzo
U.S. House of Representatives
Washington, DC 20515

Dear Representative Palazzo:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

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U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Gary Palmer
U.S. House of Representatives
Washington, DC 20515

Dear Representative Palmer:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Greg Pence
U.S. House of Representatives
Washington, DC 20515

Dear Representative Pence:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
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- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable August Pfluger
U.S. House of Representatives
Washington, DC 20515

Dear Representative Pfluger:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

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We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

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Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Guy Reschenthaler
U.S. House of Representatives
Washington, DC 20515

Dear Representative Reschenthaler:

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The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
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- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

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Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable John Rose
U.S. House of Representatives
Washington, DC 20515

Dear Representative Rose:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable John Rutherford
U.S. House of Representatives
Washington, DC 20515

Dear Representative Rutherford:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Maria Salazar
U.S. House of Representatives
Washington, DC 20515

Dear Representative Salazar:

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This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Sam Graves
U.S. House of Representatives
Washington, DC 20515

Dear Representative Graves:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

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Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Steve Scalise
U.S. House of Representatives
Washington, DC 20515

Dear Representative Scalise:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

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- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Austin Scott
U.S. House of Representatives
Washington, DC 20515

Dear Representative Scott:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

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The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Mike Simpson
U.S. House of Representatives
Washington, DC 20515

Dear Representative Simpson:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
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- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Jason Smith
U.S. House of Representatives
Washington, DC 20515

Dear Representative Smith:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Peter Stauber
U.S. House of Representatives
Washington, DC 20515

Dear Representative Stauber:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Elise Stefanik
U.S. House of Representatives
Washington, DC 20515

Dear Representative Stefanik:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Chris Stewart
U.S. House of Representatives
Washington, DC 20515

Dear Representative Stewart:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

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The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Claudia Tenney
U.S. House of Representatives
Washington, DC 20515

Dear Representative Tenney:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

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Update on Current Situation

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable GT Thompson
U.S. House of Representatives
Washington, DC 20515

Dear Representative Thompson:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable William Timmons
U.S. House of Representatives
Washington, DC 20515

Dear Representative Timmons:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

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- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
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- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Fred Upton
U.S. House of Representatives
Washington, DC 20515

Dear Representative Upton:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable David Valadao
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Washington, DC 20515

Dear Representative Valadao:

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The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

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Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Jeff Van Drew
U.S. House of Representatives
Washington, DC 20515

Dear Representative Van Drew:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Beth Van Duyne
U.S. House of Representatives
Washington, DC 20515

Dear Representative Van Duyne:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
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- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Ann Wagner
U.S. House of Representatives
Washington, DC 20515

Dear Representative Wagner:

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U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Tim Walberg
U.S. House of Representatives
Washington, DC 20515

Dear Representative Walberg:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

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Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

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Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Jackie Walorski
U.S. House of Representatives
Washington, DC 20515

Dear Representative Walorski:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

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- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
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- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Michael Waltz
U.S. House of Representatives
Washington, DC 20515

Dear Representative Waltz:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Daniel Webster
U.S. House of Representatives
Washington, DC 20515

Dear Representative Webster:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

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What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Brad Wenstrup
U.S. House of Representatives
Washington, DC 20515

Dear Representative Wenstrup:

Thank you for your letter of May 11, 2022, cosigned by several of your colleagues, to the Food and Drug Administration (FDA or the Agency) regarding the shortage in the availability of infant formula. Ensuring that parents and caregivers have access to safe and nutritious infant formula is of utmost importance to the Agency. FDA remains committed to closely monitoring the availability of all types of infant formula and is working diligently to support the supply of infant formula products using all of its available tools. As requested in your letter, Agency staff are available to discuss our infant formula supply chain monitoring and mitigation efforts, as well as additional tools that would be helpful to prevent, monitor, and mitigate any future infant formula shortages.

The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

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We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Roger Williams
U.S. House of Representatives
Washington, DC 20515

Dear Representative Williams:

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The infant formula supply chain is controlled by a small number of producers who have a handful of manufacturing facilities – which means that any perturbation or cause for a facility to halt production will lead to disruption in supply. Further, FDA would need both additional authorities and resources to create a robust supply chain monitoring program for this critical product, which serves as the sole source of nutrition for infants. Despite this, FDA has taken aggressive steps to intervene and bolster infant formula supplies due to Abbott's voluntary recall of infant formula on February 17, 2022.

FDA believes that the safe restart of production at Abbott, the increased production of other manufacturers, and the arrival of additional products under FDA's recently issued infant formula flexibility guidance – all working in concert together – will steadily improve availability on store shelves over the coming days and weeks. FDA will keep your offices closely updated on this.

Your letter raises questions that fall into four broad areas, which we address below.

Update on Current Situation

Increasing the availability of safe infant formula is of the utmost importance to FDA. We are doing everything in our power as part of the all-of-government efforts to ensure there is adequate product available wherever and whenever parents and caregivers need it. FDA began alerting federal partners and stakeholders about potential supply disruptions even before Abbott voluntarily recalled product. Just after, FDA reached out to infant formula manufacturers to seek

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

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FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

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FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
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FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

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In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

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Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

May 24, 2022

The Honorable Rob Wittman
U.S. House of Representatives
Washington, DC 20515

Dear Representative Wittman:

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more supply chain insight and to increase production. FDA has since met regularly with federal partners and worked with stakeholders to mitigate supply disruptions and bolster supply. FDA has also leveraged IRI data to monitor in-stock rates of formula and has been working to get more of the right formulas to the right places where families, parents, and caregivers need them.

Importantly, on May 16, 2022, a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott principals, was entered in the U.S. District Court for the Western District of Michigan. FDA sought a negotiated consent decree with Abbott because FDA lost confidence in the firm's food safety culture, but also knew that a rapid restart of production at Sturgis was critical to address the supply of specialty metabolic formulas, amino acid formulas, and regular formulas. Under the consent decree, Abbott has agreed to take corrective actions following the FDA inspection of its Sturgis facility. The consent decree obliges Abbott to take actions that are expected to ultimately result in an increase of infant formula products, while also ensuring that the company undertakes actions that would ensure safe powdered infant formula is produced at the facility. When the company decides to restart production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem and conduct a root-cause investigation before resuming production. Under the consent decree, Abbott Nutrition is required to retain an independent expert to review the Sturgis facility's operations to ensure compliance with the law. The consent decree also includes requirements for testing products, as well as the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Abbott has been aware of the sanitation and equipment issues that the firm needed to correct since FDA closed the inspection and issued a 483 to the firm on March 18, 2022. FDA is in close touch with Abbott, and we are eagerly awaiting the firm to resume production.

Also on May 16, FDA announced a guidance that outlines increased flexibilities regarding importation of certain infant formula products to further increase the availability of infant formula across the country while protecting the health of infants. The Agency is encouraging infant formula manufacturers worldwide to take advantage of these flexibilities. Within the first days following this announcement, we received multiple requests and hope that more companies seeking to take advantage of these flexibilities will submit information for FDA to quickly evaluate whether the product can be used safely and whether it provides adequate nutrition. We have already issued two enforcement discretion letters – and hope to issue more soon. The information that will help us review these requests expeditiously includes labeling, information on nutritional adequacy and safety testing, and information about facility inspection history. The Agency is prioritizing submissions for products that can demonstrate the safety and nutritional adequacy and have the largest volume of product available and/or those who can get product onto U.S. shelves the quickest. FDA has also worked with federal partners to airlift additional amino acid and hypoallergenic hydrolyzed formula from Nestle facilities in Europe; the amino acid formulas arrived in Indiana on May 22, 2022, and the hydrolyzed formula is expected to arrive later this week.

FDA also has been in discussions with formula manufacturers and suppliers regarding additional supply throughout our response, and infant formula manufacturers are all reporting that they are producing at an expanded capacity. In fact, Gerber has reported that it increased the amount of

their infant formula available to consumers by approximately 50 percent in March and April and Reckitt is supplying more than 30 percent more product year to date.

This increased production is now evident in increased infant formula sales. According to data from Information Resources Inc. (IRI), national infant formula sales by volume for the month of April were up more than 13 percent compared to the month prior to the recall and national infant formula sales by unit for the month of April are also up by more than 5 percent compared to the month prior to the recall.

While some data suppliers have reported lower in-stock rates, the most complete data sets available from IRI are showing nearly 80 percent in-stock rates at the week ending May 15. This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate would translate to 40 of those 50 product types being available.

What the sales volume data and in-stock rates tell us is that while there is more product being sold, it may be of less variety than prior to the recall. With increased production by other manufacturers, additional import actions, and the potential for Abbott Nutrition's Sturgis facility to resume production in the near-term, FDA expects supply to continue to steadily improve in the coming days and weeks.

FDA Actions to Date

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall that began on February 17, 2022, due to pandemic-related issues (worker absenteeism due to COVID-19, labor challenges, ingredient shortages, and logistical bottle necks). Thus, even prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition Sturgis facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Specifically, FDA was in communication with infant formula manufacturers and the Infant Nutrition Council of America (INCA) before the recall to discuss supply chain challenges and seek out real time feedback of the status of the marketplace. Additionally, during the pandemic and still ongoing, FDA has been working with manufacturers to review, as expeditiously as possible, their data submissions related to minor changes, mostly in ingredients and packaging, in their products stemming from supply chain issues which helps to alleviate any unnecessary disruptions to the supply that might otherwise have occurred.

To help increase the current supply of infant formula, FDA is leveraging all of the tools at its disposal. The Agency continues to take several significant actions, including:

- Meeting regularly with major infant formula manufacturers to better understand their capacity to increase production of various types of infant formulas and medical foods. The infant formula industry is working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly the specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 *Forward* food supply chain continuity system, combined with external data (more information below).
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Expediting the necessary certificates to allow for flexibility in the movement of already permitted products from abroad into the U.S. Currently, FDA has reviewed and expedited two USDA export certificates which helped to bring additional infant formula into the U.S. market. After the publication of the guidance to manufacturers of infant formula about temporary enforcement discretion, we expect that number to grow.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues (e.g., product labeled "Not for Individual Sale" or product with the incorrect manufacturing location identified, while other tracking and contact information is correct) for both domestic and imported products to help increase volume of product available as quickly as possible.
- Reaching out to retailer stakeholder groups to request that their members consider placing purchase limits on some products in order to protect infant formula inventories for all consumers.
- Worked to prioritize the release of metabolic and amino acid formulas produced at the Sturgis facility and asked Abbott to develop a process to provide access in critical conditions. Abbott Nutrition has allowed individuals needing urgent, life-sustaining supplies of certain specialty and metabolic formulas to access these formulas on a case-by-case basis that have been on hold at its Sturgis facility (more information below).

FDA understands that availability of specialty products such as amino acid-based specialty formulas and metabolic products continues to be of concern. In fact, FDA prioritized the metabolic products stored at the Sturgis facility and agreed with Abbott to exclude them from the recall given they serve as a sole source of nutrition for infants with rare diseases and disorders, and we knew there were limited or no alternatives available. FDA asked Abbott to develop a process to release these products, and Abbott is allowing their case-by-case release in consult with healthcare providers. The risk of not having certain specialty and metabolic products available could significantly worsen underlying medical conditions, and in some cases, pose life-threatening risks for individuals who rely on these products. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA is working to ensure health care

provider associations and stakeholders understand information about the risks and benefits of pursuing this product.

Meanwhile, these products have been an area of focus for discussions with other manufacturers that make comparable products. As a result of the recall and work with FDA, other manufacturers have increased production of comparable product lines and in some cases expedited the importation of these products where they exist.

Stakeholder Outreach

In addition to frequent calls with infant formula manufacturers domestically and abroad, FDA has been in communication with the families, health care providers, and other Department of Health and Human Services (HHS) programs affected by the infant formula shortage. We are partnering with the United States Department of Agriculture's Food and Nutrition Service (FNS) to monitor the impact of the recall on the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program. FDA has also been in communication and working with associations of healthcare professionals such as the American Academy of Pediatrics, the American Society of Pediatric Nephrology, and Genetic Metabolic Dietitians International to identify possible alternatives to the affected formulas and provide information that may be helpful to their members in working with individual parents and caregivers. FDA has also been in communication with support and advocacy groups for individuals with inherited metabolic disorders regarding Abbott's program to provide limited release of its specialty formulas for such conditions on a case-by-case basis for individuals in dire need. These additional stakeholder groups include the Society of Inherited Metabolic Disorders and the Maple Syrup Urine Disease Family Support Group.

Supply Chain Monitoring

Monitoring the supply of infant formula availability has been key to informing our response and helping the Agency focus on the areas of greatest need. FDA is monitoring the availability of infant formula products using a data analytics platform called 21 *Forward*, combined with external data. 21 *Forward* was developed during the pandemic to provide a comprehensive, data-backed understanding of how the pandemic is impacting all nodes in the food supply chain, from producers and growers to grocery stores. Although originally designed to address the broader food supply during the pandemic, the Agency has adapted it for monitoring and supporting infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales. Combining these various sources of data has provided FDA with as full a picture as possible on the current and future status of supply.

This information has helped guide numerous discussions with industry on how to increase production of various types of infant formulas and medical foods. Manufacturers' efforts are already underway to maximize production to meet demand, including optimizing production lines and packaging to increase capacity; prioritizing product lines that are of greatest need (particularly for specialty formulas); expanding hours of operation for manufacturing facilities; and expediting the importation of product produced at facilities located abroad.

Strengthening data tool sets at FDA and in other agencies is critical to enhancing infant formula supply chain resiliency. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. However, funding for 21 *Forward* expires in September 2022, and our external data purchases are short-term. FDA is interested in exploring options to continue this program into the future.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain. Building resiliency across the infant formula supply chain will better-enable us to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long-term.

We also have identified legislative changes in the President's fiscal year (FY) 2023 budget request that would provide new tools to help FDA prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, which would allow the Agency to receive timely and accurate information about likely or confirmed shortages in the U.S. marketplace, better enabling us to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition. In light of the current situation, we have also begun considering what additional tools would be helpful to prevent, monitor, and mitigate any future infant formula shortages. We would be happy to discuss with you or your staff once we have more information available.

We understand the stress and anxiety that this shortage is causing parents and caregivers. We're working with industry 24/7 to do all that we can so that consumers can find the products they need, where they shop, and when they need them. We will keep your offices closely updated as we continue our actions to bolster the supply of formula, and hope to work with you on additional tools that will allow FDA to do more. An identical response has been sent to your cosigners.

Sincerely,

Kimberlee R. Trzeciak -S

Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.05.24 17:09:34 -04'00'

Kimberlee Trzeciak
Associate Commissioner
for Legislative Affairs

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Congress of the United States
House of Representatives
Washington, DC 20515

May 17, 2022

Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf,

Parents and families across the country are feeling the effects of the shortage of infant formula. Infant formula is a critical tool in ensuring that children's nutritional needs are met. The Centers for Disease Control and Prevention report that only 25.8% of infants are exclusively breastfed by the time they are 6 months old. Without access, parents are left with few options to keep their children healthy. My home state of Oregon is facing a 34% out-of-stock rate, resulting in severe consequences from price gouging to milk banks not being able to serve low-income families. As the Food and Drug Administration (FDA) encourages the importation of infant formula from outside the United States and the domestic distribution of formula produced for export, I urge you to swiftly provide guidance to manufacturers that would assist them as they look at this temporary pathway.

The monopoly that the three major manufacturers have on the current market has led us to this current moment. Consistent with the Biden-Harris Administration's efforts to promote competition in the American economy, allowing more producers to enter the market will ease shortages and make the market more competitive. I recently heard from a local manufacturer, Cascadia Nutrition, who produces infant formula that meets quality standards at an FDA-approved facility in the United States but because they have not undergone clinical trials, they can only distribute this product internationally. They are among a number of smaller manufacturers who have the production capability and supply to meet the current needs.

In the wake of the FDA's announcement, expedited guidance could provide clarity for those companies that seek to domestically distribute product manufactured for export. If there is product produced in the United States and safely consumed by children abroad, it is my view that it should also be able to be distributed in the United States. Smaller companies that do not have

the resources to undergo clinical testing but adhere to the same quality metrics as larger companies should not be penalized at this critical moment and, more importantly, neither should our communities. The FDA must work with these manufacturers to utilize their sorely-needed supply in accordance with applicable laws and regulations.

Thank you for your consideration.

Sincerely,

Earl Blumenauer
Member of Congress

United States Senate
Washington D.C. 20510

May 18, 2022

VIA ELECTRONIC TRANSMISSION

The Honorable Robert Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, M.D. 20993

Dear Commissioner Califf:

Thank you for your efforts to ensure food safety at the Food and Drug Administration (FDA). For decades, the FDA has been the gold standard for approving and regulating medical products and food. Yet this year, the actions of the FDA's Center for Food Safety and Applied Nutrition (CFSAN) has raised questions regarding its ability to fulfill its core oversight responsibilities. The safety of, and access to, infant formula should be among CFSAN's highest priorities, as this food is vital for the growth and development of infants. To this end, we write to request a response from FDA on its activities that may have contributed to the exacerbated infant formula shortages and specific questions in the following paragraphs. It is our responsibility as U.S. Senators to do everything with our authority to hold the FDA accountable and legislate in areas that will enable the agency to meet the expectations of the American people.

Our hearts and prayers are with the parents and their families whose babies tragically died due to infant formula bacterial contamination. We understand and want to support the FDA in thoroughly evaluating all reported and potential infant formula contaminations. However, based on the timeline and where we are today, it is unclear as to why nearly three months have gone by and the FDA has failed to expeditiously conduct and conclude its investigation. On February 17, Abbott Nutrition initiated a proactive, voluntary recall of three of its powdered formulas manufactured at their facility in Michigan following four consumer complaints of potential *Cronobacter* bacteria contamination.[1]

[1] Abbott, Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant, February 17, 2022, https://abbott mediaroom.com/2022-02-17-Abbott-Voluntarily-Recalls-Powder-Formulas-Manufactured-at-One-Plant. *See* also U.S. Food and Drug Administration, Company Announcement: Abbott Voluntarily Expands Recall of Powder Formulas Manufactured at One Plant, February 17, 2022, https://www fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant.

The following day, FDA warned consumers not to use these products.[2] On April 15, the U.S. Centers for Disease Control and Prevention concluded the bacteria isolated from two of the sick infants and the Michigan facility had no connection. And as of last week, no connection has been found, yet the facility remains idle.[3, 4]

We are also concerned as to why FDA leadership failed to be proactive in mitigating the shortage crisis parents are now facing. The COVID-19 pandemic revealed many vulnerabilities across all sectors of industry, and our food supply chain was woefully unprepared to handle challenges here and from foreign partners. Infant formula supplies at local grocery stores were relatively stable for the first half of 2021. The out-of-stock percentage started to climb steadily in the later half and continued to worsen throughout this year.[5] Abbott Nutrition's voluntary recall exacerbated the shortage, and yet no policies were taken to mitigate the sharp increases to the current out-of-stock 43 percent the Administration is now scrambling to address. It's also concerning that FDA and key officials in the Administration did not anticipate this crisis or take action within days following Abbott Nutrition's voluntary recall considering the company holds 48.1 percent of the U.S. market in infant formula.[6]

Families are getting to the brink of pursuing unsafe and potentially dangerous options to feed their infants including homemade infant formula. And physicians are, once again, running defense on misinformation due to a lack of federal action to get the word out on safe alternatives.[7, 8, 9] In addition, the shortage will trickle into other federal agencies, diverting and stretching resources from other crises like illicit fentanyl. In April, the U.S. Customers and Border Protection (CBP) seized $30,000 worth of unapproved infant formula across 17 shipments at the Philadelphia, Pennsylvania port of entry.[10]

Based on the timeline, it is unclear why federal health agencies have not been able to complete this investigation in a more expeditious manner or plan ahead to mitigate this additional supply chain disruption. Therefore we respectfully request your responses to the following questions:

1. The manufacturing facility in Michigan is segmented where manufacturing designated areas are required to adhere to specific safety and infection control standards. The facility also

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[2] Kansas Department of Health and Environment, KDHE & FDA warn consumers not to use select Similac, Alimentum & EleCare powdered infant formula, February 18, 2022, https://www.kdhe.ks.gov/CivicAlerts.aspx?AID=147.
[3] Abbott, Press Release: Abbott Provides Infant Formula Update, May 11, 2022, https://www.abbott.com/corpnewsroom/nutrition-health-and-wellness/abbott-update-on-powder-formula-recall html.
[4] U.S. Centers for Disease Control and Prevention, Cronobacter and Powdered Infant Formula Investigation, accessed May 12, 2022 (updated May 12, 2022), https://www.cdc.gov/cronobacter/outbreaks/infant-formula html.
[5] Datasembly, Nation-wide Out-Of-Stock is now at 43% for the week ending May 8th, May 10, 2022, https://datasembly.com/news/out-of-stock-rate-in-april-2022-copy/.
[6] IBISWorld, Industry Report: Infant Formula Manufacturing, by Jack Curran, August 2020, https://www.ibisworld.com/united-states/market-research-reports/infant-formula-manufacturing-industry/.
[7] The New York Times, Why Doctors Don't Recommend Homemade Baby Formula, by Catherine Pearson, May 11, 2022, https://www.nytimes.com/2022/05/11/well/homemade-baby-formula.html.
[8] KAKE ABC, Homemade infant formula can be dangerous. Experts share how to feed your baby through the shortage, by Madeline Holcombe, May 11, 2022, https://www.kake.com/story/46472922/homemade-infant-formula-can-be-dangerous-experts-share-how-to-feed-your-baby-through-the-shortage.
[9] Bloomberg, Parents Are Trying Homemade Baby Formula. Doctors Say They Shouldn't, by Allison Nicole Smith and Kelsey Butler, May 12, 2022, https://www.bloomberg.com/news/articles/2022-05-12/why-parents-making-homemade-infant-formula-should-beware-of-serious-health-risks.
[10] U.S. Customs and Border Protection (CBP), Philadelphia CBP Seizes Nearly 600 Cases of Infant Formula Unapproved for Import to the United States, April 5, 2021, https://www.cbp.gov/newsroom/local-media-release/philadelphia-cbp-seizes-nearly-600-cases-infant-formula-unapproved.

maintains areas that are administrative and do not directly handle manufacturing or exposure of open products. Please describe the areas in which the FDA has taken samples and how many samples were taken that would empirically validate the results of the investigation. In your explanation, please also include the expected timeline for each task and if CFSAN has met its obligations.

2. As noted in the paragraph above, the CDC concluded that the samples taken did not match the bacteria in the facility. How does the FDA partner with other agencies at the federal, state, and/or local level to expedite investigations to forestall potential supply chain crises? To what extent do other agencies or organizations advance or hinder a timely investigation?
3. Why has it taken more than three months to complete the obligations required to finalize a safety inspection?
4. At what point did the FDA alert the White House of the bacteria and the product recall?
5. Did the FDA, along with the White House, have a strategic plan in place to mitigate formula shortages? If yes, please provide a brief description, date of implementation, actions the agency has taken, and expected timelines to enable manufacturers to produce, process and deliver food during supply chain disruptions.
6. Did or has the FDA made any recommendations to the White House about what actions the agency can take to prepare or handle the shortage?
7. The manufacturing facility in Sturgis, Michigan is the only Abbott plant to produce specialized formula for infants with metabolic disorders. How is the FDA going to work with Abbott and other formula manufacturers to ensure that the special medical needs of infants can be met?
8. Abbott Nutrition, along with other infant formula manufacturers, have registered domestic and foreign sites to manufacture infant formula for interstate commerce in the U.S. Abbott Nutrition's facility in Ireland is an FDA-registered facility. It also has several other facilities in the Netherlands, Spain, and France that manufacture infant formula. What steps has FDA taken to increase importation by accrediting more manufacturing facilities overseas?
9. At what point was the White House made aware that these importation options were available to ease the strain on domestic capacity?
10. Whose decision was it to ease these requirements on formula from foreign manufacturers?
11. In White House press briefings last week, the Press Secretary and others within the Biden Administration appeared to blame Abbott Nutrition for the deaths and shortages, despite the fact that the investigation is not concluded.[11, 12] Did the FDA state to the White House that Abbott Nutrition was responsible for the illnesses or deaths?

The shortage, felt by all families in need, is disproportionately impacting vulnerable populations. As you know, Medicaid is a major source of coverage for low-income vulnerable populations including pregnant women, infants, and children. In 2020, Medicaid covered 42 percent of births.[13] In addition,

[11] The Hill, White House goes on defense on baby formula shortage, by Alex Gangitano, May 13, 2022, https://thehill.com/news/administration/3487765-white-house-goes-on-defense-on-baby-formula-shortage/.
[12] The Hill, Buttigieg points blame at Abbott for baby formula shortage, by Monique Beals, May 15, 2022, https://thehill.com/news/administration/3489439-buttigieg-points-blame-at-abbott-for-baby-formula-shortage/.
[13] March of Dimes, Health Insurance/Income, https://www.marchofdimes.org/peristats/data?reg=99&top=11&stop=154&lev=1&slev=1&obj=18.

49 percent of infants born in the U.S. participate in the Special Supplemental Nutrition Program for Women, Infants, and Children.[14] While breastfeeding has been on the rise, many infants rely on formula partially or as their sole source of food.

The FDA must do everything within its statutory authority to ensure it facilitates access to safe, quality foods. We would appreciate a reply no later than Wednesday, May 25, 2022. Thank you for your attention to this matter and please do not hesitate to reach out to us or our staff should the agency require resources or cooperation from other agencies to fulfill its obligations.

Sincerely,

Roger Marshall, M.D.
U.S. Senator

Shelley Moore Capito
U.S. Senator

Susan M. Collins
U.S. Senator

Mike Braun
U.S. Senator

John Barrasso, M.D.
U.S. Senator

Kevin Cramer
U.S. Senator

Lisa Murkowski
U.S. Senator

Jerry Moran
U.S. Senator

Marsha Blackburn
U.S. Senator

John Boozman
U.S. Senator

Bill Cassidy, M.D.
U.S. Senator

Deb Fischer
U.S. Senator

Cynthia Lummis
U.S. Senator

Tim Scott
U.S. Senator

[14] National WIC Association, The State of WIC: Investing in the Next Generation, February 2022, page 40, https://s3.amazonaws.com/aws.upl/nwica.org/state-of-wic_2022.pdf.

Thom Tillis
U.S. Senator

Cindy Hyde-Smith
U.S. Senator

John Thune
U.S. Senator

James Lankford
U.S. Senator

Steve Daines
U.S. Senator

Ted Cruz
U.S. Senator

Roy Blunt
U.S. Senator

John Kennedy
U.S. Senator