# Infant Formula Enforcement Discretion Policy: Guidance for Industry

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You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA–2022–D–0814.

For questions regarding this guidance document, contact the Center for Food Safety and Applied Nutrition, Office of Nutrition and Food Labeling, at 240-402-4487.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Food Safety and Applied Nutrition**

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This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

## I. Introduction

We are issuing this guidance document to help increase the supply of infant formula in the United States. FDA intends to temporarily exercise enforcement discretion with respect to certain requirements for infant formulas that may not comply with certain statutory and regulatory requirements and is seeking information from manufacturers regarding the safety and nutritional adequacy of their products. This guidance document is intended to:

- explain factors that FDA intends to consider in making case-by-case determinations about whether to exercise enforcement discretion to allow the introduction into interstate commerce (including importation) of infant formula that is safe and nutritionally adequate, but that may not comply with all statutory and regulatory requirements; and
- advise infant formula manufacturers about the type of information to provide to FDA, if they would like FDA to consider whether to exercise enforcement discretion with regard to particular products.

This guidance document will remain in effect until November 14, 2022, and we will evaluate whether any extension is necessary. We will give public notice when the period of enforcement discretion ends.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the

[1] This guidance has been prepared by the Office of Nutrition and Food Labeling and the Office of Regulations and Policy in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

word "should" in FDA guidance means that something is suggested or recommended, but not required.

This guidance is being issued to help increase the supply of infant formula in the United States. This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2). This guidance is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

# II. Background

The FD&C Act defines infant formula as "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk" (section 201(z) of the FD&C Act, 21 U.S.C. 321(z)). Our regulations define infants as persons not more than 12 months old (21 CFR 105.3(e)). Section 412(c)(1)(B) of the FD&C Act (21 U.S.C. 350a(c)(1)(B)) and FDA regulations (21 CFR 106.120) require an infant formula manufacturer to submit notice (i.e., a new infant formula submission) to FDA at least 90 days before the infant formula is introduced or delivered for introduction into interstate commerce.[2]

Infant formula is often used as the sole source of nutrition by a vulnerable population during a critical period of growth and development. In general, the laws and regulations that apply to food also apply to infant formula, but additional requirements that are specific to infant formula exist at section 412 of the FD&C Act and our regulations at 21 CFR parts 106 and 107. For example, under section 412(i) of the FD&C Act and our regulations at 21 CFR 107.100, an infant formula must meet specific requirements for the levels of protein, fat, essential fatty acids, 15 vitamins, and 12 minerals.

Our regulations also establish labeling requirements, such as the specific presentation and formatting of nutrient information (21 CFR 107.10) and directions for use (107.20). For example, under 21 CFR 107.20(b), the label must bear, in close proximity to the directions for preparation and use of the infant formula, a pictogram depicting the major steps for preparing the infant formula. Under 21 CFR 107.20(c), the directions for use also must have a "Use by ___" date (where the blank is filled in with the month and year selected by the manufacturer, packer, or distributor of the infant formula).

[2] We do not consider the marketing of products under any such temporary exercise of enforcement discretion to alter the status of such products as "new infant formula" under 21 CFR 106.3 for purposes of the applicability of the new infant formula registration and submission requirements under section 412(c) and (d) of the FD&C Act (21 U.S.C. 350a(c) and (d)) and 21 CFR 106.110 and 106.120.

# III. Discussion

*A. What Actions Have Been Taken to Address Infant Formula Supply?*

We are aware that a voluntary recall and facility shutdown conducted by Abbott Nutrition in 2022 has created a supply disruption with respect to certain types of infant formula, particularly given the overall strains on supply chains that have been experienced during the COVID-19 pandemic. We have taken steps to support the supply of infant formula products, including regular meetings with infant formula manufacturers to better understand their capacity to increase production, expediting review of notifications of manufacturing and packaging changes that will help increase supply (particularly for specialized formulas for medical needs), exercising enforcement discretion for minor deviations from labeling requirements, and monitoring the status of the infant formula supply (see FDA Takes Important Steps to Improve Supply of Infant and Specialty Formula Products | FDA). FDA has worked with the United States Department of Agriculture (USDA) to ensure Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) program participants and stakeholders have information needed to keep infants safe and USDA has offered new flexibilities to WIC program participants to increase their options for obtaining needed infant formulas.

On May 12, 2022, the President announced that FDA would take new steps concerning importing certain infant formula products from abroad (see FACT SHEET: President Biden Announces Additional Steps to Address Infant Formula Shortage | The White House).

The steps taken by the President and by FDA seek to increase the overall supply of nutritionally adequate infant formula while maintaining nutritional adequacy and product safety. Towards that end, this guidance document discusses our intent to consider, on a case-by-case basis, the temporary exercise of enforcement discretion from certain statutory and regulatory requirements.

*B. What Does This Guidance Document Do?*

In brief, this guidance document describes the information that an infant formula manufacturer should provide to us if the infant formula manufacturer wishes to have FDA consider the exercise of enforcement discretion relating to the introduction into interstate commerce (including importation) of infant formula that is safe and nutritionally adequate but may not comply with all FDA statutory and regulatory requirements. We will use the information to consider whether to exercise enforcement discretion and the extent of that enforcement discretion.

The extent to which we exercise enforcement discretion may vary. For example, an infant formula whose label does not list the nutrients in the order required by 21 CFR 107.10(a) would need an exercise of enforcement discretion regarding that particular labeling requirement, and FDA may determine that enforcement discretion is appropriate. In contrast, an infant formula whose level for a specific nutrient is below the minimum that we require or does not contain a specific nutrient we require might not be an appropriate candidate for enforcement discretion, especially if the low level or absence of the nutrient could present a safety issue for infants. Certain labeling requirements (for example, the clear identification of any allergens present on

the product label or adequate instructions for safe product preparation and use) have a connection to safety and will receive special attention as we consider requests for enforcement discretion.

*C. Who Might Seek Enforcement Discretion?*

This guidance document may be of interest to:

- Infant formula manufacturers who manufacture infant formula for export in domestic facilities;
- Infant formula manufacturers who presently do not export infant formula manufactured in foreign facilities to the United States; and
- Infant formula manufacturers who may be able to provide infant formula to help address shortages by changing production site(s), changing production practice(s), or making other changes to an existing infant formula.

*D. What Information Should an Interested Infant Formula Manufacturer Send to FDA?*

We recommend that infant formula manufacturers (as described in part III.C) send the following information to us:

- For each **infant formula product**:
    - The infant formula's specific name and other product identification information. Information on the number and size of retail containers also would be helpful. Other identifying information should include, as applicable, batch and lot number(s), product identification codes (such as universal product code (UPCs) or stock keeping unit (SKU) numbers). If the product has been previously notified to FDA, the product identification number (IFN) should be provided;
    - The names of the countries where the product is currently marketed and how long the product has been in that market;
    - The quantity of the product intended for introduction into commerce. At a minimum, the quantity should be expressed by weight;
    - Whether the quantity intended for introduction into interstate commerce is in the infant formula manufacturer's current inventory. If so, please provide the product's "use by" date. If the product is not in the current inventory, the infant formula manufacturer should provide the date on which it would plan to introduce the product into interstate commerce or import into the United States. It also will be helpful to indicate whether a one-time shipment or multiple shipments are intended;
    - The name(s) and location(s) of the manufacturing facilities where the specified batches/lots are made;
    - If available, the infant formula manufacturer's distribution plan(s), down to the retail level;
    - The infant formula's full quantitative formulation, which is a list of all ingredients and the amount of each ingredient in units per absolute amount (such as milligrams per 1000 gram of infant formula or grams per liter of infant formula);
    - A copy of the product's label;

  - A description of the product's packaging;
  - For the most recent batch/lot produced at each applicable facility, a summary of test results, conducted at the final product stage, of the level of each nutrient required by our regulations at 21 CFR 107.100 and, for nutrients not required by our regulations, but added by the infant formula manufacturer, a summary of the test results presented in units per 100 kilocalories. For specialized formula that may not meet all nutrient requirements, provide an explanation for why the deviation from the nutrient requirements is necessary to provide an infant formula that is appropriate for the dietary management of a specific disease, disorder, or medical condition; and
  - For powdered infant formula, for the most recent batch/lot produced at each applicable facility, a summary of all test results for *Cronobacter* spp. and *Salmonella* spp., conducted at the final product stage. For *Cronobacter* spp., we recommend testing 30 samples, with each sample being 10 grams; for *Salmonella* spp., we recommend testing 60 samples, with each sample being 25 grams. We also ask for a description of the test method used (such as our *Bacteriological Analytical Manual*) and a copy of the method. For example, a certificate of analysis with information listed in 21 CFR 117.165(b)(2) from a qualified laboratory may be one way to convey these test results.
- For each **manufacturing facility**:
  - A certification that the manufacturer has established current good manufacturing practices, including quality control procedures and in-process controls, and testing required by current good manufacturing practice, designed to prevent adulteration of formulas produced at that facility. Also provide a schematic diagram (i.e., process flow diagram) with processing times and temperatures in addition to a written narrative that includes, but is not limited to, a summary of the process flow, heating and processing conditions, and critical control points; and
  - As applicable, the FDA Food Facility Registration number. If the manufacturing facility has not received an FDA inspection, then the date of the last inspection by the relevant government authority (or a third-party audit conducted by a qualified auditor on behalf of a government authority), a summary of the findings, and any actions taken by the manufacturer in response. In the latter instance, the standards/regulations against which the inspection was conducted should be clearly identified.

*E. Where Should the Information be Sent?*

The information described in part III.D of this guidance document should be sent in English to Infant_formula_flexibility@fda.hhs.gov. We will handle the information consistent with our obligations under 21 CFR part 20, "Public Information." For example, as a general matter, trade secrets and confidential commercial information are not available for public disclosure (see 21 CFR 20.61(c)).