

Timeline of infant formula related activities

2020

- **11 March 2020** – World Health Organization declares COVID-19 a pandemic.
- **16 March 2020** – FDA begins to have concerns about infant formula and special medical food shortages given their production at a small number of facilities controlled by a handful of firms. FDA identifies a need for supply chain authorities and begins to draft a legislative proposal.
- **21 March 2020** – FDA submits a legislative proposal to Congress requesting supply chain authority for infant formula and special medical foods.
- **September 2020** – FDA stands up a proof-of-concept food supply chain monitoring system called 21 Forward to monitor the food supply chain for disruptions despite lack of dedicated funds or authorities. FDA initially uses the system to monitor for supply chain disruptions related to COVID-19, including infant formula-related disruptions. For example, we contacted an infant formula plant in a COVID rapid riser community in an attempt to minimize disruption.

2021

- **June 2021** – FDA requests infant formula and special medical food supply chain authorities in its FY 2022 budget request. FDA also requests funding for four additional infant formula staff.
- **20 – 24 September 2021** – FDA conducts a routine surveillance inspection at Abbott Nutrition’s Sturgis, Michigan, facility. The FDA investigator searched the Agency’s database for related consumer complaints days prior to inspection. FDA made five observations – including standing water and inadequate handwashing.¹
- **20 September 2021** – FDA receives a consumer complaint report of *Cronobacter* illness in an infant from the Minnesota Department of Health (Case Complaint #1). The illness onset was 6 September 2021.
- **21 September 2021** – FDA informs Abbott Nutrition of the *Cronobacter* complaint it received (Case Complaint #1). Minnesota Department of Health sent product samples to CDC for sequencing earlier in September.
- **23 September 2021** – FDA collects product samples from the hospital where the patient was treated. The sample was sent to FDA’s Southeast Food and Feed Laboratory for analysis (Case Complaint #1).
- **6 October 2021** – FDA’s Southeast Food and Feed Laboratory reports no *Cronobacter* findings in samples (Case Complaint #1).
- **10 October 2021** – Minnesota Department of Health sends patient clinical sample to CDC (Case Complaint #1).

¹ U.S. Food and Drug Administration, “Form 483: Inspectional Observations; Abbott Nutrition, Sturgis, Michigan Facility,” September 20-24, 2021, available at https://www.fda.gov/media/156747/download?utm_medium=email&utm_source=govdelivery.

- **21 October 2021** – FDA receives a complaint from a confidential informant electronically. Complaint is reviewed by multiple FDA staff. FDA acknowledges receipt. FDA begins planning for an inspection at Abbott Nutrition’s Sturgis facility.
- **26 October 2021** – FDA Detroit District Office receives a hard copy of a complaint from a confidential informant. FDA leadership do not receive direct copies of the complaint due to an isolated failure in FDA’s mailroom, likely due to COVID-19 staffing issues.

FDA Staff in Receipt of Complaint; Dates of Receipt	
William Weissinger (Office of Human and Animal Food Operations-East Division 6, District Director, Office of Regulatory Affairs (ORA))	21 October 2021 – Received via email 26 October 2021 – Received via FedEx
Dr. Andrea Lotze (Medical Director, Infant Formula and Medical Foods Staff, CFSAN)	20 October 2021 – Received via email*
Cathy Hermsen (Assistant Commissioner for Criminal Investigations, ORA)	3 November 2021 – Alerted to existence by FDA staff 5 November 2021 – Received via USPS (FEDEX package with complaint)
Dr. Judith McMeekin (Associate Commissioner for Regulatory Affairs)	14 February 2022 – Received via email (forwarded from FDA staff)*
Dr. Susan Mayne (Director, CFSAN)	14 February 2022 – Received via email*
Dr. Janet Woodcock (then-Acting FDA Commissioner)	14 February 2022 – Received via email (forwarded from FDA staff)*
*Hard copies addressed to these individuals were not forwarded from the FDA mailrooms, likely due to COVID-19-related mail routing issues. In May 2022, the CFSAN mailroom located copies of the complaint sent to Susan Mayne and Andrea Lotze via FedEx and forwarded to these individuals. The copies of the complaint sent via FedEx to Judith McMeekin and Janet Woodcock have not been located to date but a mailroom analysis is underway.	

- **4 November 2021** – FDA Office of Human and Animal Food Operations (OHAFO) staff discuss confidential informant complaint with FDA’s Office of Criminal Investigations.
- **8 November 2021** – FDA OHAFO staff discuss confidential informant complaint with the investigator and National Expert Investigator (whose expertise includes infant formula and medical food inspections) who inspected Sturgis facility in September 2021.
- **17 November 2021** – FDA receives a consumer complaint of a *Salmonella* illness potentially associated with an Abbott Nutrition powdered infant formula. After investigation, CDC and FDA eventually rule this case as unrelated to Abbott Nutrition.
- **1 December 2021** – FDA receives a consumer complaint of a *Cronobacter* death potentially associated with Abbott Nutrition powdered infant formula (Case Complaint #2). The date of illness onset was 20 November 2021. No positives for *Cronobacter* were among formula samples collected by FDA for follow-up testing.
- **2 December 2021** – FDA notifies Abbott Nutrition of the *Salmonella* and second *Cronobacter* consumer complaints (as previously noted, FDA and CDC later decide the *Salmonella* case is not related to Abbott Nutrition). FDA collected and analyzed product samples but did not find *Cronobacter* or *Salmonella*. No clinical isolate was available for the *Cronobacter* case.
- **7 December 2021** – FDA requests to interview the confidential informant, but due to scheduling limitations associated with the informant, the interview was not scheduled until 22 December 2021.

- **22 December 2021** – FDA interviews the confidential informant. This information informs the inspection that occurs in January 2022.
- **30 December 2021** – FDA contacts Abbott Nutrition to schedule a 3 January 2022 inspection pursuant to the Agency’s policy to preannounce inspections during the COVID-19 pandemic. Abbott Nutrition requests FDA delay the inspection due to an ongoing COVID-19 outbreak among its staff. FDA agrees to a delay.

2022

- **11 January 2022** – FDA receives a third *Cronobacter* illness complaint (Case Complaint #3). The date of illness onset was 18 December 2021. Samples collected by the Texas Department of State Health Services do not test positive for *Cronobacter*. This is the second case with a clinical isolate sample available for comparison to environmental samples that will be taken during FDA’s inspection later this month at the Sturgis facility.
- **27 January 2022** – FDA contacts Abbott Nutrition to announce our intention to proceed with an inspection. Abbott Nutrition informs FDA of a continued COVID-19 outbreak among its employees.
- **31 January – 18 March 2022** – FDA proceeds with an inspection of Sturgis plant despite the COVID-19 outbreak given the fact pattern indicating a potential issue. FDA finds significant, fundamental sanitation, building, and equipment issues and takes multiple environmental samples.²
- **7 February 2022** – Seven of FDA’s environmental swabs suggest the potential presence of *Cronobacter*, but require confirmatory testing.
- **9 February 2022** – FDA leadership informed of potential positive samples, defined as “Cannot Rule Out” (unconfirmed) taken during the inspection of Abbott Nutrition’s Sturgis plant.
- **10 February 2022** – Food Program Leadership meets, and FDA’s Coordinated Outbreak Response Network begins coordinating a response.
- **11 February 2022** – FDA notifies USDA’s WIC program of potential action that could impact the infant formula supply.
- **13 February 2022** – FDA sequences six confirmed samples of *Cronobacter* collected from Abbott Nutrition’s Sturgis facility environment during the recent inspection. Nineteen additional samples are being sequenced.
- **14 February 2022** – An FDA intra-agency group, including experts and leadership from OFPR and CFSAN, begins discussions of food safety, regulatory, and supply chain issues related to the response. FDA updates USDA WIC on the investigation status.
- **15 February 2022** – FDA recommends Abbott Nutrition voluntarily recall product. FDA receives additional *Cronobacter* sample results, meets with USDA WIC on the investigation, potential for a recall, and supply chain issues. Abbott Nutrition voluntarily ceases production. FDA seeks, and Abbott Nutrition agrees to, exclude and hold specialty metabolic products given the critical access need and Abbott Nutrition’s lack of a mitigation plan to produce these formulas at one of its other facilities.

² U.S. Food and Drug Administration, “Form 483: Inspectional Observations; Abbott Nutrition, Sturgis, Michigan Facility,” January 31-March 18, 2022, available at https://www.fda.gov/media/157073/download?utm_medium=email&utm_source=govdelivery.

- **16 February 2022** – FDA again recommends Abbott Nutrition voluntarily recall product. FDA, as a Co-Sector Risk Management Agency of the Food and Agriculture Sector, submits a report to U.S. government (USG) partners on the potential recall and supply chain impacts given the significant market share held by Abbott Nutrition, as well as the Sturgis facility being a critical producer of specialty metabolic and amino acid formulas. FDA begins discussion with Abbott Nutrition on additional testing for these held products and a strategy to release products to those in dire need. FDA meets with the American Academy of Pediatrics to make them aware of a significant upcoming action involving infant formula that will have ramifications for supply chains. We share that our communications would advise parents to consult with the child’s health care provider for advice, with additional communications forthcoming from FDA.
- **17 February 2022** – Following a third recommendation by FDA that Abbott Nutrition voluntarily recall product, FDA issues a consumer advisory warning consumers to avoid certain Abbott Nutrition products as Abbott Nutrition voluntarily recalls product. FDA begins regular reports and coordination with USG partners on supply chain. CDC notifies FDA of a fourth case that may be related. Daily situation reports begin for FDA staff and leadership working on the response. FDA requests from IRI infant formula in-stock rates at the national level, which was not previously tracked by FDA. FDA requests that FMI, the Food Industry Association (FMI) ask retailers to limit sales to no more than five cans per shopper; FMI recommends the limit to retailers later that day.
- **18 February 2022** – FDA receives a fourth *Cronobacter* case report of a death potentially associated with Abbott Nutrition product (Case Complaint #4). FDA contacts other infant formula manufacturers to discuss actions to address potential supply chain disruptions. The date of illness onset for this case was 4 January 2022. No clinical isolate is available, and product samples do not test positive for *Cronobacter*. FDA requests an independent expert conduct a batch review of held specialty metabolic product.
- **22 February 2022** – First infant formula data sets obtained by FDA from IRI.
- **24 February 2022** – Russia invades Ukraine. This leads to additional uncertainty in the infant formula supply chain as Ukraine is a major exporter of sunflower oil, an ingredient used in many infant formulas. Manufacturers begin to re-assess their supplies and make plans in consultation with FDA about possible substitutions.
- **28 February 2022** – Abbott Nutrition voluntarily expands its recall at FDA’s recommendation to cover additional products associated with the fourth case complaint.
- **Late February – early March 2022** – FDA meets with retailers and other infant formula manufacturers throughout this period on actions to address infant formula supply chain and to seek supply chain information. FDA continues regular coordination with manufacturers. FDA follows up on several additional *Cronobacter* complaints but eventually determines them unrelated to Abbott Nutrition. Actions ultimately result in significant increases in domestic production by late April and early May.
- **15 – 16 March 2022** – FDA inspection team returns to Sturgis facility to obtain additional records related to complaints received. FDA receives FY 2022 additional funding to hire four additional infant formula staff.
- **18 March 2022** – January 2022 inspection and related sampling activities conclude. Inspection is closed, and FDA issues its inspection observations (FDA Form 483).³ Observations from inspection and FDA’s lack of confidence in Abbott Nutrition’s food safety culture inform FDA’s decision to negotiate a consent decree with the goal of addressing these observations and safely resuming production at Sturgis as soon as possible.
- **28 March 2022** – FDA’s FY 2023 budget request includes infant formula and medical foods supply chain legislative proposal.

3 U.S. Food and Drug Administration, “Form 483: Inspectional Observations; Abbott Nutrition, Sturgis, Michigan Facility,” January 31-March 18, 2022, available at https://www.fda.gov/media/157073/download?utm_medium=email&utm_source=govdelivery.

- **31 March 2022** – Abbott Nutrition provides FDA the independent batch review of specialty metabolic product requested 18 February.
- **1 April 2022** – FDA transforms response activity to an Agency-wide Incident Management Group to manage the response, including supply chain.
- **20 April 2022** – FDA communicates to Abbott Nutrition our decision not to object to release of specialty metabolic product broadly after enhanced finished product testing, and not to object to release on case-by-case basis for urgent need. This was communicated to Abbott Nutrition again on 20 April and 28 April.
- **29 April 2022** – FDA issues an updated advisory to ensure consumers are aware of Abbott Nutrition’s process to release metabolic formulas on a case-by-case basis, in consultation with a healthcare provider, to those families who have no alternative supply.
- **16 May 2022** – FDA and Abbott Nutrition sign a proposed consent decree.
- **16 May 2022** – U.S. District Court for the Western District of Michigan enters the consent decree. FDA issues enforcement discretion guidance to provide flexibilities to boost the supply of infant formula.
- **20 May 2022** – FDA issues its first enforcement discretion letter for a specialty infant formula product. FDA is evaluating additional requests for enforcement discretion. FDA is working with USG partners to arrange air transport for amino acid and hypoallergenic hydrolyzed formulas to arrive in the United States on 22 May 2022.