U.S. FOOD & DRUG ADMINISTRATION

FDA FACT SHEET

Status Update | March 2023
FDA's Infant Formula Response Activities

Since the Abbott infant formula recall in February 2022, the U.S. Food and Drug Administration (FDA or the Agency) and U.S. government partners have been working to expand consumer access to infant formula products, while also ensuring that these products meet the agency's safety, nutrition, and quality standards. As we emerged from the acute crisis, the agency conducted numerous reviews including an evaluation of the agency's infant formula response and the Reagan-Udall foundation's Evaluation of the FDA's Human Foods Program (conducted at FDA's request) to identify areas for improvement within the Agency. While work continues on all fronts, the FDA is committed to transparency. Below is an update on actions the FDA has taken, and those underway, to strengthen the safety and resiliency in the supply of nutritious infant formula.

Safety of Infant Formula

- In 2022, FDA conducted 34 inspections of foreign and domestic facilities that produce infant formula (including some that also produce medical foods), meeting FDA's inspection targets for FY22. Appropriate follow up actions were taken as warranted. Importantly, FDA had set targets to inspect facilities that produce infant formula annually, even prior to a requirement to do so established in the Food and Drug Omnibus Reform Act of 2022.
- In November 2022, FDA released a draft outline of a strategy to prevent *Cronobacter sakazakii* illnesses associated with the consumption of powdered infant formula. This outline was intended to guide discussions with stakeholders over the next several months as FDA further developed the strategy.
    - FDA concluded all meetings with infant formula manufacturers throughout January and February 2023 to discuss the strategy, learn more about what industry is doing to enhance safety, and hear their ideas for prevention.
    - In March 2023, as part of the prevention strategy work, FDA sent a letter to the powdered infant formula industry to share current safety information and call on the industry to take prompt action to improve processes and programs for the protection of our most vulnerable population.
- In November 2022, the FDA advanced a charge through the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service's National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to gain scientific insight on possible industry and public health interventions to address *Cronobacter* infections associated with powdered infant formula.
- Initiated engagement with the Council of State & Territorial Epidemiologists (CSTE) and Centers for Disease Control and Prevention (CDC) about elevating reporting for *Cronobacter* infection in infants less than 1 year of age to a nationally notifiable disease.
- FDA has expanded the availability of education materials to help consumers better understand *Cronobacter* risks associated with powdered infant formula and the steps they can take at home to help minimize any potential contamination.
- FDA continues to work with Abbott Nutrition under the consent decree entered by the U.S. District Court for the Western District of Michigan on May 16, 2022. This consent decree requires Abbott to take the steps necessary to safely produce infant formula in close coordination with FDA and under our oversight of its manufacturing and food safety processes.

Resiliency in the Supply of Nutritious Infant Formula

- At the height of the supply challenges, FDA staff worked daily with clinicians and hospitals to address crucial issues of specialty and medically necessary formula supply for infants with serious metabolic diseases who were dependent on highly specialized formulas.
- FDA supported our colleagues at HHS to mobilize Operation Fly Formula to arrange for emergency air transport of large volumes of formula at the peak of the crisis.
- FDA worked with Customs and Border Protection (CBP) to implement legislation that provided temporary relief for infant formula importers from tariffs during the latter half of 2022.
- FDA has helped to expand access to infant formula by temporarily exercising enforcement discretion, on a case-by-case basis, for certain infant formula requirements. Twelve manufacturers have brought various infant formula products into the U.S. market under FDA's exercise of enforcement discretion, doubling the number of firms suppling product to the U.S. market from 2021 to 2022.
    - FDA conducted an expedited review of certain food safety and nutrition records associated with the firms and products prior to issuing letters of enforcement discretion.
    - FDA also adjusted import screening criteria to help facilitate the immediate importation of millions of pounds of infant formula and infant formula base powder (an ingredient used in producing infant formula products).
- FDA also issued the Infant Formula Transition Plan for Exercise of Enforcement Discretion guidance that outlines a path for interested firms marketing products in the U.S. under the exercise of enforcement discretion to bring those products into compliance with U.S. requirements to facilitate longer-term supply resiliency in the U.S. market.
    - During October and November 2022, FDA hosted a four-part webinar series to provide detailed information about the transition plan for infant formulas marketed under the exercise of enforcement discretion and to address questions.
- FDA has leveraged 21 Forward, a tool that was built to help track supply chain shortages during the COVID-19 pandemic, to now inform ongoing work to track and anticipate supply disruptions across the infant formula supply chain. The platform uses data provided to the agency voluntarily by infant formula manufacturers.
    - FDA staff continue to meet regularly with infant formula manufacturers to discuss current and forecasted production and to identify potential distribution issues.
- The Agency coordinated with colleagues in the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR) Defense Production Act (DPA) Office to leverage their capabilities and authority to identify and provide appropriate support to resolve raw material constraints on ingredients needed to manufacture formula – including through technical assistance and DPA authorities when needed.

Operational Improvements

- FDA has revised its internal consumer complaint procedure to strengthen the escalation process to better define when certain consumer complaints need to be escalated to senior officials. This change involves rapid escalation of reports of serious illness or death to the highest levels of the agency and specifically addresses triggers for any hospitalization or death involving an infant.
- FDA has significantly expanded and improved a required infant formula online training course for investigators and other appropriate staff to ensure every infant formula inspection is robust, thorough, and focused on the most critical aspects of the infant formula manufacturing process.
- The Office of Regulatory Affairs (ORA) has significantly expanded the agency's capacity to analyze samples

of infant formula by adding two laboratories with the capacity to test for *Cronobacter*, partnering with state laboratories with existing capabilities, and enhancing its system for prioritizing sample analysis.

- FDA staff who conduct or support inspections of powdered infant formula manufacturers attended an interactive in-person powdered infant formula inspection workshop with specific training on conducting infant formula inspections in January 2023. The workshop provided critically relevant and timely inspectional information for investigators and other appropriate staff, including updates from lessons learned during previous inspections.
- In February 2023, CFSAN issued a schedule with instructions for improved routine surveillance inspections and sampling to be conducted at domestic and foreign infant formula and medical food facilities in fiscal year (FY) 2023. These instructions, issued to FDA investigators, included numerous modifications that incorporate lessons learned during inspections conducted in FY22 and address feedback from internal and external stakeholders.
    - In 2022, prior to FDA's evaluation of the infant formula response, CFSAN began amending its instructions to ORA related to inspections of infant formula and medical food facilities. The changes provided additional considerations for environmental sampling, a renewed focus on the supply chain requirements under the Preventive Controls for Human Food Rule, and scheduling adjustments to minimize potential supply chain disruptions.
- CFSAN's Office of Nutrition and Food Labeling has increased its staff by 66 percent to better facilitate infant formula reviews.

New Authorities

While FDA has taken actions to improve access to safe and nutritious infant formula, there also has been widespread recognition that new authorities, provided by Congress, could help to build a lasting foundation for a more resilient infant formula supply in the U.S. The FDA is currently designing implementation plans for new authorities received in the Food and Drug Omnibus Reform Act of 2022, including:

- Creating a new Office of Critical Foods responsible for oversight, coordination, and activities related to critical foods, which is defined as infant formula and medical foods.
- Expediting review of premarket infant formula submissions if an infant formula shortage has been identified.
- Mandating critical foods manufacturers to notify FDA of a permanent discontinuance or interruption that is likely to lead to a meaningful disruption in infant formula supply.
- Requiring critical foods manufacturers to develop, maintain and implement, as appropriate, redundancy risk management plans to identify and evaluate risks to the supply of the critical food, such as infant formula, and ways to mitigate such risks.
- Issuing guidance to support new infant formula submissions.
- Exploring pathways to harmonize international regulatory requirements for infant formula.
- Notifying Congress of infant formula recalls.
- Working with relevant federal agencies to work together to develop a National Strategy on Infant Formula to address infant formula supply chain resiliency and provide education and communication for parents and caregivers.
- Engaging with the National Academy of Science, Engineering and Medicine to examine and report on challenges in the supply, market competition, and regulation of infant formula in the U.S.

FDA also received expanded hiring authorities under the 21st Century Cures Act to recruit additional staff to, among other things, support the infant formula work underway and implement new infant formula authorities provided for in the Food and Drug Omnibus Reform Act of 2022.

FDA is also seeking additional authority through the FY24 budget request to require that, among other things, manufacturers report to FDA final product positive test results for relevant pathogens, conduct more frequent environmental monitoring in their facilities to identify relevant pathogens, and maintain the results of such testing for FDA inspection, either in person or remotely. The combination of these new authorities would empower the FDA to work with firms in real time to resolve issues around product positive findings and better assure the safety of product entering the market.

The FDA appreciates the continued collaboration with the infant formula industry, retailers, educators, and federal partners to strengthen the resiliency and safety of infant formula in the United States.