U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

July 13, 2026

Dear Infant Formula Industry:

This letter is directed to manufacturers, packagers, distributors, exporters, importers, and retailers involved in the manufacturing or distribution of infant formula and infant formula ingredients. The U.S. Food and Drug Administration (FDA) is issuing this letter in response to several serious public health events, including two multistate outbreaks of infant botulism linked to powdered infant formula as well as cereulide intoxication associated with a contaminated ingredient in infant formula. These events highlight risks that manufacturers should consider when selecting ingredients and ingredient sources for powdered infant formula production.

Infant formula, whether used exclusively or in combination with breastfeeding, is an essential source of nutrition for many infants in the United States. The consequences of safety failures in this product category are severe and, in some cases, life-threatening. FDA holds infant formula manufacturers to the highest standards of safety and quality. This responsibility extends to every ingredient, every supplier, and every link in the supply chain. This letter calls for increased vigilance by industry to ensure ingredient and infant formula safety.

Infant Botulism Outbreaks: A Common Thread

FDA has investigated two multistate outbreaks of infant botulism associated with two separate brands of powdered infant formula – ByHeart, Inc., and Nara Organics, Inc. – resulting in voluntary recalls.

The multistate outbreak associated with ByHeart powdered infant formula was the first botulism outbreak definitively tied to infant formula in the United States since infant botulism was first described as a distinct clinical entity nearly 50 years ago. As part of its investigation, FDA inspected ByHeart's manufacturing facilities. These inspections led to the identification of *Clostridium botulinum* in organic whole milk powder used as an ingredient. FDA also conducted an inspection and collected samples at Dairy Farmers of America, Inc., the processor for Organic West Milk, which supplied ByHeart. Two samples from one lot of organic whole milk powder matched a clinical sample and an infant formula sample by whole genome sequencing (WGS). FDA's ongoing investigation into the root cause is focused on ingredients and their production environments.

On June 13, 2026, FDA announced an investigation of a multistate outbreak of infant botulism in which all affected infants had consumed Nara Organics-brand powdered infant formula. Nara Organics subsequently voluntarily recalled all lots of its powdered infant formula due to the risk of *Clostridium botulinum* contamination. FDA has confirmed that Organic West Milk also supplied

U.S. Food and Drug Administration
Human Foods Program
5001 Campus Drive
College Park, MD 20740
www.fda.gov

Nara Organics. FDA's investigation is ongoing.

Cereulide Intoxication: Ingredient Contamination

These botulism outbreaks do not stand alone. From December 2025 to February 2026, nearly 150 suspected and confirmed cases of cereulide intoxication were reported across 10 countries, resulting in global recalls of infant formula contaminated with cereulide – a toxin produced by *Bacillus cereus* – traced to contaminated arachidonic acid (ARA) oil. On May 2, 2026, the a2 Milk Company voluntarily recalled certain batches of its imported a2 Platinum Premium powder infant formula 0-12 months from the United States market due to the presence of cereulide. On May 12, 2026, all ARA oil products, including ARA oil powder, from CABIO Biotech (Wuhan, China) became subject to FDA Import Alert 99-51, which provides for Detention Without Physical Examination of human food products that appear to have been prepared, packed, or held under insanitary conditions resulting in chemical contamination.

Manufacturer Responsibility: Know Your Suppliers

Taken together, these events – two infant botulism outbreaks potentially linked to a shared dairy ingredient supplier and a global contamination event linked to an ARA supplier – reflect a pattern that warrants attention from both FDA and the infant formula industry. In each case, the risks were introduced through the supply chain. In each case, the consequences fell on infants.

As FDA stated in its March 2023 Letter to the Powdered Infant Formula Industry, suppliers of raw materials or other ingredients that will not receive a lethal treatment at the infant formula manufacturing facility are an extension of the infant formula manufacturing process. This principle is the foundation of the regulatory framework governing infant formula manufacturing.

Under 21 CFR Part 106, infant formula manufacturers must maintain production and in-process controls across all stages of processing from the receipt of raw materials through the distribution of finished product. This includes developing and enforcing ingredient specifications, quarantining and dispositioning ingredients that fail to meet those specifications, and conducting regularly scheduled audits to verify compliance with current good manufacturing practices (CGMPs) and quality control procedures.

Under 21 CFR Part 117, infant formula manufacturers and their supply chain partners must develop and implement a food safety plan that includes a hazard analysis, preventive controls, and, if applicable, a risk-based supply chain program. Firms that are subject to the requirements of Subpart G of Part 117 must identify and evaluate hazards associated with raw materials and ingredients, approve suppliers, and conduct appropriate supplier verification activities, such as onsite audits by qualified auditors, for ingredients where a supply-chain-applied control has been identified.

Further, FDA recommends that infant formula manufacturers and their supply chain partners stay abreast of applicable recall notifications, outbreak investigations, and import alerts, which may serve as a safety signal (e.g., that an identified ingredient or supplier presents risk). Experience has shown that ignoring or downplaying these safety signals can lead to public health events that could have been avoided. FDA expects manufacturers to exercise substantive oversight of their suppliers, including understanding where their ingredients come from, how they are produced,

what risks they may carry, and whether those risks are being effectively controlled, as appropriate, by the supplier. When a contaminated ingredient or supplier concern is identified – whether by FDA or through industry's own monitoring – manufacturers are expected to act swiftly to assess and address the risk.

Additionally, under section 424(b) of the FD&C Act (21 U.S.C. 350m(b)), as added by the Food and Drug Omnibus Reform Act of 2022, infant formula manufacturers are required to develop, maintain, and implement, as appropriate, a redundancy risk management plan that identifies and evaluates risks to the supply of infant formula for each establishment in which it is manufactured. FDA expects manufacturers to treat this requirement as a meaningful supply disruption risk management tool.

Resources

We are aware of challenges in managing the risks related to spore forming microbes in ingredients used to produce infant formula and that there might not be a single approach for managing the risks. We are prepared to work with industry to identify best practices for managing the risks as we solicit advice from experts. This includes FDA's ongoing investigations into the root causes of the 2025 and 2026 infant botulism outbreaks associated with powdered infant formula. To that end we have:

- **Supported the Codex Committee on Food Hygiene (CCFH)** to request scientific advice from the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) related to *Clostridium botulinum* and *Bacillus cereus* in powdered infant formula. This included risk assessments and other relevant scientific advice that would inform recommendations on strengthened control measures across the production environment. It covered all stages from primary production and packaging through to the reconstitution of the product, including environmental monitoring programs.

- **Engaged with external researchers** on various topics related to infant botulism and the presence and potential control measures for *Clostridium botulinum* on dairy farms and in milk and milk powders.

- **Engaged with Cornell University's Pathogenic Spore Consortium,** a cohort of leaders across academia and industry addressing the risks posed by spore forming bacteria in dairy production, as they develop strategies and training for dairy producers to reduce the presence of *Clostridium botulinum* and other spore-formers in milk.

- **Requested the International Commission on Microbiological Specifications for Foods (ICMSF)** to consider revisiting its publication "Usefulness of testing for *Clostridium botulinum* in powdered infant formula and dairy-based ingredients for infant formula" given the recent infant botulism outbreaks in the U.S.

FDA has published guidance documents and resources to assist manufacturers in meeting their obligations to monitor the infant formula supply chain:

- FDA's website: Information for Infant Formula Manufacturers and Retailers
- Regulations and Information on the Manufacture and Distribution of Infant Formula

- Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food
- Draft Guidance for Industry: Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event
- FDA Calls for Enhanced Safety Measures in Letter to Powdered Infant Formula Industry
- Information on Redundancy Risk Management Plans for Critical Food Manufacturers

Conclusion

Infant formula safety is a shared responsibility that begins with manufacturers and their suppliers. Infants are a uniquely vulnerable population, and infant formula, whether used exclusively or in combination with breastfeeding, is a critical source of nutrition for many infants. FDA expects the infant formula industry to know its suppliers, enforce its ingredient standards, and take proactive, verifiable steps to ensure that the ingredients entering its facilities do not introduce avoidable risk. When a contaminated ingredient or supplier concern is identified, manufacturers are expected to act swiftly to assess and address that risk. FDA will continue to use all available tools to protect infants, and we expect industry to uphold these standards to meet that commitment with the gravity our shared responsibility demands. FDA appreciates the industry's increased vigilance and continued commitment to ensuring the safety of infant formula products marketed in the United States.

Sincerely,

/S/

Donald A. Prater, DVM
Acting Deputy Commissioner for Food
Human Foods Program