U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

January 14, 2026

Safe Food Coalition
1620 I Street, NW, Suite 200
Washington, DC 20006

Dear Safe Food Coalition Members:

Thank you for your December 8, 2025, letter regarding infant formula safety in light of the ongoing *Clostridium botulinum* outbreak linked to ByHeart infant formula. The Food and Drug Administration (FDA or "We") share your commitment to protecting our nation's most vulnerable consumers and appreciate your recommendations for strengthening FDA's inspection and regulatory oversight of infant formula. Ensuring that the infant formula supply is safe and wholesome for children and their families who rely upon these products is a top priority for the Department of Health and Human Services (HHS) and FDA. Operation Stork Speed, announced in March 2025, reaffirms our commitment to ensuring the ongoing quality, safety, nutritional adequacy, and resilience of the domestic infant formula supply.

Upon learning of a potential botulism outbreak linked to ByHeart infant formula in early November 2025, FDA, in close coordination with the Centers for Disease Control and Prevention (CDC) and state and local partners, worked swiftly to identify the source of the outbreak and initiate a recall.

FDA's investigation is ongoing to determine the point of contamination, and additional testing by ByHeart, FDA, CDC, and state partners is underway. Results are expected in the coming weeks and the outbreak advisory will be updated as information, including positive samples results, becomes available.

As we learn more about this outbreak, it is important to note that there are fundamental differences between spore-forming bacteria like *Clostridium botulinum* and vegetative bacteria such as *Cronobacter* and *Salmonella,* which is crucial for understanding food safety contamination risks and assessing testing strategies. These two categories of bacteria present distinct contamination risks and require different prevention and testing strategies due to their vastly different survival capabilities and environmental presence. These are important considerations as we continue to respond to this outbreak and implement risk reduction strategies going forward.

Below are the actions FDA is currently taking to respond to this outbreak and strengthen infant formula safety and oversight in the United States:

Strengthening Inspections

We continue to prioritize hiring staff in this critical area, including a dedicated cadre of investigators to conduct infant formula inspections at all FDA-registered domestic and foreign infant formula

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manufacturing facilities. FDA is actively working to fill remaining investigator vacancies and has announced streamlined hiring authority for new food safety investigators.

We are also enhancing our training programs to ensure investigators have the specialized expertise needed for infant formula oversight. FDA conducts annual surveillance inspections at all domestic and foreign infant formula facilities and conducts additional for-cause inspections when warranted by public health concerns. FDA investigators use compliance programs to help ensure inspections are consistent and all manufacturing facilities are held to the same high standards. A compliance program provides instructions and tools for FDA investigators, laboratory analysts, and compliance officers. FDA's approach to inspections, sample collection and analysis, and compliance activities helps ensure infant formula products in the U.S. are safe and wholesome. FDA revised the infant formula compliance program in September 2023, with additional updates occurring in August 2025.

Regulatory Oversight

As this represents the first documented outbreak of *C. botulinum* attributed to contaminated infant formula, our investigation is focused on understanding the root cause and contamination pathway. Gaining a clearer understanding of contributing factors in this outbreak is a significant priority and, as ongoing work is completed, FDA will evaluate whether additional preventive controls, testing protocols, or regulatory measures are warranted across the industry.

To further our understanding of spore-forming pathogen contamination, FDA strongly advocated for the request to the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) to conduct a risk assessment on spore-forming pathogens, including *C. botulinum* and *Bacillus cereus*, in powdered infant formula and the Codex Committee on Food Hygiene request to JEMRA to: 1) update the existing risk assessment and scientific advice on *Cronobacter* and *Salmonella* in powdered infant formula and 2) provide other relevant scientific advice that would inform recommendations on strengthened control measures across infant formula production, covering all stages from primary production and packaging through to the reconstitution of the product and including environmental monitoring.

Recall Effectiveness

In addition to working expeditiously with rapidly evolving case and product information to initiate and expand the recall of potentially contaminated infant formula, FDA quickly launched efforts to assess the effectiveness of the recall. We shared ByHeart's distribution lists with state and local partners with 20.88 agreements (nearly all State authorities have such arrangements in place) within three hours of receiving them. We also initiated additional processes to share distribution lists more broadly with partners without 20.88 agreements. These efforts were designed to facilitate all available entities' ability to conduct ongoing recall effectiveness checks to ensure products are removed from shelves. Over 4,000 recall audit checks were performed by FDA, state and local partners— the most ever for a specific recall event.

Based on our findings, FDA recently issued a letter reminding industry, in particular retailers, of their responsibilities to efficiently and effectively conduct recalls. This letter noted the particular importance of these responsibilities when recalling foods like infant formula or other products for infants and children. This was a companion letter to four additional warning letters sent to retailers based on recall effectiveness issues seen during the ByHeart infant formula recall.

Collaborating with CDC and State Partners

We recognize the critical role CDC's food safety surveillance plays in outbreak detection and prevention and support adequate funding for these vital programs. In this unprecedented outbreak, we also recognize the vital role of the California Department of Public Health and the Infant Botulism Treatment and Prevention Program. We continue to work closely with CDC and state partners on surveillance and response efforts.

Congressional Authorities

We continue to leverage the full spectrum of authorities Congress has provided for infant formula oversight and appreciate the additional authorities received through the Food and Drug Omnibus Reform Act (FDORA). We recognize that certain enhanced authorities, such as those in currently proposed and contemplated legislation, could further strengthen FDA's oversight capabilities. In addition, in recent budgets FDA has included legislative proposals requesting authorities to strengthen its oversight of critical foods, including authorities to require reporting to FDA of positive test results for certain pathogens in infant formula even if the product has not been distributed and require industry to conduct robust environmental monitoring in infant formula production facilities.

Thank you again for your letter and your ongoing commitment to infant formula safety. As we share the goal of protecting our nation's most vulnerable consumers, we welcome the opportunity to discuss these efforts further with your members.

Sincerely,

Kyle Diamantas, J.D.
Deputy Commissioner for Human Foods
Human Foods Program