SAFE FOOD COALITION

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December 8, 2025

Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Martin A. Makary, M.D., M.P.H.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Jim O'Neil
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Re: Infant formula

Dear Secretary Kennedy, Commissioner Makary, and Acting Director O'Neil:

The undersigned members of the Safe Food Coalition write to urge you to take immediate steps towards ensuring infant formula safety following the outbreak of *Clostridium botulinum* infections linked to infant formula manufactured by ByHeart, Inc. Swift action is needed to avoid future outbreaks and further disruptions to the supply of this critical product. The ongoing infant botulism outbreak linked to infant formula, with 37 confirmed cases so far, has exposed dangerous deficiencies in the inspection and regulatory systems that should ensure the safety of the nation's youngest and most vulnerable consumers.

To correct these deficiencies, we respectfully request that you direct the staff at the U.S. Food and Drug Administration and the Centers for Disease Control and Prevention to:

I. Strengthen inspection by:
   - Filling inspector vacancies (currently at 40 percent)
   - Reinstating FDA's inspector training program
   - Increasing inspection of infant formula facilities
   - Fully funding inspections, including funding for state inspections

II. Strengthen regulation by:

- Declaring *Clostridium botulinum* contamination in infant formula to be a hazard requiring preventive controls, and updating the agencies' approach to *Clostridium botulinum* contamination, including under the FDA Food Safety Modernization Act (FSMA) Preventive Controls Rule
- Developing recommendations for best practices to avoid *Clostridium botulinum* contamination in infant formula based on a root cause assessment of the ongoing outbreak
- Conducting a sampling program for *Clostridium botulinum* in infant formula
- Issuing recommendations to companies on appropriate testing for indicator organisms

III. Facilitate swift recalls by promptly sharing information with state enforcement agencies

IV. Fully fund food safety work conducted in CDC's National Center for Emerging and Zoonotic Infectious Diseases within the Division of Foodborne, Waterborne, and Environmental Diseases, including vital foodborne illness surveillance activities like FoodNet

V. Request new authority from Congress

These reforms are long overdue. In 2022, two infant deaths caused by *Cronobacter sakazakii* infection sparked recalls and closure of the Abbot Labs Sturgis, Michigan production facility, which in turn triggered a nationwide shortage of infant formula.[1] In response, Congress created the Office of Critical Foods within FDA,[2] and CDC worked with state and local partners to make *Cronobacter* infection a nationally notifiable disease.[3] Despite these incremental advances, consumer protections against contaminated infant formula remain woefully inadequate, with infant formula production and packaging facilities typically inspected at most once a year. Often providing the sole source of nutrition for newborns and infants, infant formula should meet more rigorous safety standards and more frequent inspections.

I. Strengthen Inspection

The current outbreak, linked to ByHeart infant formula, underscores the ongoing need to bolster inspection resources. FDA inspection records indicate that the ByHeart production facility in Reading, Pennsylvania exhibited signs of unsanitary conditions like mold and insect infestations.[4] Greater scrutiny of ByHeart's entire operation, including the Allerton, Iowa production facility linked to the ongoing outbreak, may have prompted an earlier recall and avoided illnesses. However,

[1] Cronobacter Outbreak Linked to Powdered Infant Formula. (September 29, 2025). Centers for Disease Control. https://www.cdc.gov/cronobacter/outbreaks/formula-2022/index.html

[2] Mitchell, J. (December 15, 2023). FDA Advances Reorganization Proposal for Unified Human Foods Program. *Quality Assurance & Food Safety Magazine*. https://www.qualityassurancemag.com/news/fda-advances-reorganization-proposal-for-unified-human-foods-program/

[3] Reiley, L. (June 29, 2023). States and CDC to track cronobacter cases like other infectious diseases. *The Washington Post*. https://www.washingtonpost.com/business/2023/06/29/cronobacter-cdc-infant-formula/

[4] Jewett, C., & Creswell, J. (2025, November 13). Infant Formula Company Tied to Botulism Outbreak Had Known Problems. *The New York Times*. https://www.nytimes.com/2025/11/13/health/infant-formula-botulism.html

with 40 percent of infant formula and other "critical foods" inspector positions vacant, [5] FDA has limited capacity to redirect inspection resources in response to unsanitary conditions like the ones found at ByHeart. Cuts to the agency's administrative staff and laboratory scientists, as well as new bureaucratic hurdles in the budget approval process, have reportedly limited the effectiveness of the inspectorate that remains.[6]

These are not the only FDA staff cuts that threaten to compromise infant formula safety. FDA's Office of Training, Education, and Development (OTED) formerly managed training for both state and federal inspectors, but funding for that office was dramatically reduced during the FDA reorganization of the Human Foods Program (HFP) initiated in 2024. The reorganization plans contemplated that the HFP would manage the specialized training of inspectors carrying out food-related inspections, including those of infant formula manufacturers. Unfortunately, a reduction in force earlier this year led to the elimination of the training office in the HFP. OTED is now the sole training office and is unprepared and under-resourced to train the influx of new food safety inspectors needed to carry out work to oversee the manufacture of infant formula and the other specialized food inspection work. While the Administration has announced its intention to hire new food safety inspectors "under a stream-lined hiring authority,"[7] it should expand on those efforts to restore training and support staff at the agency, and fully fund the FDA inspection program, including funding for state inspection. Finally, with adequate inspection resources, FDA should establish new protocols that ensure infant formula manufacturers can expect an inspection on more than an annual basis, and timely follow-up inspections to verify that any non-compliance is promptly corrected.

II. Strengthen Regulation

In addition to inspection reforms, FDA should revise its rules and guidance to improve infant formula safety. In particular, the agency should declare *Clostridium botulinum* contamination to be a hazard requiring preventive controls, which manufacturers must address in their food safety plans. The agency should develop recommendations for best practices to avoid *Clostridium botulinum* contamination based on a root cause assessment of the ongoing outbreak, and conduct a sampling program testing infant formula for *Clostridium botulinum*. Operation Stork Speed should include increased testing for microbiological contaminants, as well as for heavy metals and nutritional adequacy.[8] Finally, FDA should offer guidance to companies on incorporating recommendations for routine testing for *Clostridium botulinum* indicator organisms, which were drafted by the International Commission on Microbiological Specifications for Foods in 2014.[9]

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[5] Tin, A. (June 6, 2025). FDA food inspector vacancies near 20% after Trump hiring freeze. *CBS News*. https://www.cbsnews.com/news/fda-food-inspector-vacancies-trump-hiring-freeze/

[6] Ibid.

[7] Investigator II: Department of Health and Human Services. (June 6, 2025). USAJOBS. https://www.usajobs.gov:443/job/838350400

[8] HHS, FDA Announce Operation Stork Speed to Expand Options for Safe, Reliable, and Nutritious Infant Formula for American Families. (March 19, 2025). Food and Drug Administration; FDA. https://www.fda.gov/news-events/press-announcements/hhs-fda-announce-operation-stork-speed-expand-options-safe-reliable-and-nutritious-infant-formula

[9] Usefulness of testing for *Clostridium botulinum* in powdered infant formula and dairy-based ingredients for infant formula. (2014) International Commission on Microbiological Specifications for Foods. International Union of Microbiological Societies. https://www.icmsf.org/wp-content/uploads/2018/02/ICMSF_Infant_Formula_Testing_Revision1-20140117.pdf.

III. Facilitate Swift Recalls

FDA should investigate the underlying cause of delays that have hampered the recall of ByHeart formula.[10] Weeks after the announcement of the current, expanded recall, FDA has reported that major retailers including Walmart and Target are continuing to sell the product.[11] Notably, a lengthy process was reportedly needed before FDA would agree to release the names of retailers to state regulators, a process that can and must be streamlined not just with respect to recall communication, but for all communication with state regulators.[12]

IV. Fully Fund Food Safety at CDC

CDC's food safety program played a vital role in solving the ByHeart outbreak, but is not adequately resourced to carry out its mission. This inadequate funding was reflected recently in cuts to the agency's FoodNet surveillance system, which was scaled back dramatically from covering eight foodborne pathogens to only two (*E. coli* and *Salmonella*). CDC's role in foodborne disease surveillance extends beyond FoodNet to support efforts all over the United States. Roughly half of the agency's food safety budget has traditionally been distributed to the state and local agencies that form the backbone of surveillance efforts. These investments play a pivotal role in prevention. Identification of illness clusters leads to outbreak detection which, in turn, leads to root cause analyses that inform good manufacturing practices that, in turn, improve the safety of the food supply. Without adequate funding, however, this feedback loop breaks down. Indeed, the current outbreak suggests there is ample room to improve foodborne illness surveillance, with recent reports indicating that at least six babies in California had consumed ByHeart Formula and been treated for infant botulism in the nine months before officials identified the outbreak.[13] This is yet another reason why the Administration should support a 50 percent increase to the CDC's food safety budget, as outlined in a November 17 letter that Safe Food Coalition members joined with food industry stakeholders.[14]

V. Request New Authority from Congress

Finally, the agencies should work with Congress to establish adequate authority and funding to create effective infant formula protections. Bills to do this include:

- The Federal State and Food Safety Information Act, which would allow FDA to share timely information with the states to conduct recall checks;
- The Protect Infant Formula from Contamination Act, which would require companies to report positive test results in infant formula to the FDA;

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[10] Young, A. (November 21, 2025). FDA delays left recalled baby formula on store shelves, food safety expert says. Healthbeat. https://www.healthbeat.org/2025/11/22/byheart-baby-formula-recall-fda-delays/

[11] Neal, D. (November 23, 2025). Recalled baby formula still sold by Walmart, Kroger, Target, others, FDA says. *AOL*. https://www.aol.com/articles/recalled-baby-formula-still-sold-185030303.html

[12] *Supra* note 10

[13] Aleccia, J. (November 22, 2025). Babies who drank ByHeart formula got sick months before botulism outbreak, parents say. *AP News*. https://apnews.com/article/byheart-infant-formula-botulism-recall-9971f57a2a218eac4fba53f305dcba3c

[14] Letter from Consumer and Food Safety Advocacy Organizations to U.S. Secretary of Health and Human Services, Robert F. Kennedy, Jr. regarding Restoring the Foodborne Diseases Active Surveillance Network. (November 17, 2025). https://consumerfed.org/testimonial/food-industry-consumer-advocates-write-in-support-of-cdc-food-safety-program/

- The Improving Newborns' Food and Nutrition Testing Safety (INFANTS) Act, which would require additional product and environmental testing for formula, mandate reporting of product positives, facilitate remote records access, and provide additional recall authority; and
- The Baby Food Safety Act of 2024, which would require environmental monitoring in facilities producing formula and baby food.

Infant formula presents a food safety challenge with high stakes for the nation's most vulnerable consumers. We would appreciate the opportunity to meet with you and your staff to discuss ways the Department can better protect the general public—and newborns and infants in particular—and to learn more about your ideas for improving overall food safety.

Sincerely,

Center for Food Safety
Center for Science in the Public Interest
Consumer Federation of America
Consumer Reports
Government Accountability Project
Institute for Food Safety and Nutrition Security, George Washington University
Stop Foodborne Illness