

United States Senate

WASHINGTON, DC 20510-1011

July 30, 2026

Kyle A. Diamantas, J.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Diamantas:

I write to express my concern regarding reports of recent outbreaks of infant botulism. The recalls of ByHeart Whole Nutrition Infant Formula and Nara Organics Powdered Infant Formula mark two outbreaks within the past year involving reports of *Clostridium botulinum*, the bacterium that causes infant botulism.¹ Infant formula is a critical source of nourishment for newborns, regardless of whether the formula is used exclusively or as a supplement. Every parent wants to ensure that their infants are being fed in a way that is both safe and healthy. As a United States Senator, it is my duty to ensure robust oversight of the infant formula supply chain to protect Georgia families.

According to the Centers for Disease Control and Prevention's (CDC) 2025 Early Childhood Nutrition Report, 27% of Georgia's breastfed infants born in 2022 were fed formula within the first two days of life.² For the safety of Georgia's infants, I ask that you please provide an answer to the following questions, in writing, within two weeks:

1. What measures is the FDA taking to address the recent outbreaks of infant botulism linked to *Clostridium botulinum* contamination?
2. Is the FDA developing or planning to issue updated guidance for manufacturers on preventing *Clostridium botulinum* contamination?
3. Is the FDA coordinating with the United States Department of Agriculture (USDA) or other relevant agencies on dairy hygiene guidance for infant formulas that contain dairy milk?
4. What is the FDA's current inspection schedule for infant formula manufacturing facilities? For the facilities associated with the recent infant formula contamination

¹ U.S. Food & Drug Administration, (2026, June) Post-Outbreak Response Activities: *Clostridium botulinum* Illnesses Associated with Consumption of Powdered Infant Formula, <https://www.fda.gov/food/outbreaks-foodborne-illness/post-outbreak-response-activities-clostridium-botulinum-illnesses-associated-consumption-powdered>

U.S. Food & Drug Administration, (2026, June) Outbreak Investigation of Infant Botulism: Powdered Infant Formula, <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-powdered-infant-formula-june-2026>

² Centers for Disease Control and Prevention, (2025) CDC's Early Childhood Nutrition Report 2025, <https://www.cdc.gov/nutrition/media/pdfs/2025/CDC-Early-Childhood-Nutrition-Report-State-2025-508.pdf>

incidents, when was each facility last inspected, and if any routine inspections were delayed or missed, what factors contributed to those delays?

Thank you for your prompt attention to these questions. I look forward to your response.

Sincerely,



Jon Ossoff
United States Senator