

United States Senate

WASHINGTON, DC 20510

April 8, 2022

The Honorable Robert Califf, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Califf:

We write today to express our concern about the recent recall of powdered infant formula manufactured at Abbott Nutrition's facility in Sturgis, Michigan due to reports of bacterial contamination affecting Similac, Alimentum and EleCare powdered formulas, and to request information on the Food and Drug Administration's (FDA) plans to investigate these illnesses and deaths and prevent other infants from falling ill.¹ A parent should never have to worry about whether the food they feed their child is safe, let alone deadly, and we are heartbroken by news that infections linked to these products may have contributed to at least four infant hospitalizations and the tragic deaths of two of these babies.

We were alarmed to learn that reports of adverse events linked to the recalled infant formula were reported as early as September 2021, nearly five months prior to Abbott Nutrition's decision to initiate a recall. This delay was unacceptable; for nearly half a year, potentially contaminated product remained on store shelves and in baby bottles, subjecting unsuspecting families to unacceptable risk. Earlier actions to issue a recall and provide information to consumers could have prevented the subsequent three known cases, including two deaths in Ohio, reported in connection with the recalled products² or limited the quantity of recalled product and resulting shortages. The deaths of these two infants is tragic and unacceptable, and should never have happened.

In addition to our deep concerns over the health risks to infants that the potential contamination and delayed action have caused, we are alarmed by the challenges families now face in securing safe infant formula with which to feed children reliant on this important source of nutrition. Reports over shortages at grocery stores and food pantries³ due to supply chain issues preceded the current recall,⁴ which has exacerbated the already-dire situation and left parents and caregivers scrambling to secure infant formula or quickly identify alternative products.⁵ While

¹ <https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutrition-facility>; <https://abbott.mediaroom.com/2022-02-17-Abbott-Voluntarily-Recalls-Powder-Formulas-Manufactured-at-One-Plant>

² <https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022>; <https://www.cdc.gov/cronobacter/outbreaks/infant-formula.html>

³ https://www.thetimes-tribune.com/news/business/recall-magnifies-infant-formula-shortage-in-scranton-elsewhere/article_4487541d-ec8b-5a8b-b5a1-b211df46f14c.html

⁴ <https://www.wsj.com/articles/baby-formula-is-hard-to-find-brands-and-stores-are-divided-over-why-11641983401>

⁵ <https://www.washingtonpost.com/lifestyle/2022/02/23/formula-recall-fda-elecare-allergy/>

many infant formulas are interchangeable from a health or regulatory perspective, parents of infants who rely on formula to supplement breastmilk or as a sole source of nutrition find that in practice, infants often prefer certain formulations. Additionally, some infants develop allergies or sensitivities that require the use of specific formulas to ensure the infant's continued health and growth; at least one of the products associated with the Sturgis facility was a specialized formula for babies with low iron deficiencies. Furthermore, infant formula is expensive, and the sudden drop in supply caused by the recall is likely to drive up prices even further. The prospect of finding a new formula as a result of the recall has posed a logistical, financial and emotional burden for families across the U.S.

As you are aware, the FDA is responsible for overseeing manufacturers of infant formulas. Parents, caregivers, and the greater public rely upon the FDA to ensure infant formula on the shelves in our grocery stores and food pantries is safe to consume and supports healthy growth.⁶ It is unacceptable that FDA was made aware of complaints and positive cases related to the Abbott Nutrition facility months before Abbott finally issued its voluntary recall of potentially contaminated infant formula, yet failed to alert the public, immediately initiate an inspection, or demand Abbott issue an immediate recall of these infant formula products.

Better understanding the actions of and authorities utilized by the FDA in this troubling situation will help us to more quickly address and resolve the current challenge and prevent future detrimental threats to infant health. We respectfully request the FDA's response to the following questions:

1. What is the current status of the FDA's investigation into the contaminated infant formula?
2. What steps is the FDA taking to ensure enough infant formula remains on the shelves for infants and their families to rely on despite the shortage caused by the ongoing Abbott Nutrition recall? How is the FDA working with parents, health care providers, WIC programs, other HHS programs and other stakeholders to help notify parents and caregivers about the recalled products, and assist parents and caregivers in identifying and locating suitable alternatives to the affected formulas? How can parents be sure that the formula remaining on store shelves is safe?
3. When can parents expect the situation to be resolved, and when will there again be adequate supply and access availability to the products they and their children rely on?
4. When was the FDA first notified about potential illnesses linked to infant formula, and what actions were taken in response to this report?
5. What steps has the FDA taken to provide information to other families and caregivers in impacted states, including Pennsylvania and Ohio, to prevent further use of potentially contaminated product?
6. Did Abbott Nutrition fulfill all reporting requirements in connection to the complaints of adverse events? Is there information that the company could have voluntarily reported that would have allowed the FDA to respond in a more timely or effective manner?
7. How did the FDA work with Abbott Nutrition to initiate their voluntary recall? Given the serious threat of *Cronobacter sakazakii* infections, and the report of deaths linked to use of the recalled products, why was the recall voluntary, rather than mandatory?

⁶ <https://www.fda.gov/consumers/consumer-updates/infant-formula-safety-dos-and-donts>; Federal Food, Drug, and Cosmetic Act (21 USC et seq.)

8. Although the FDA typically inspects infant formula manufacturing sites annually, we understand that no such inspection of Abbott Nutrition’s Sturgis facility was conducted in 2020.⁷ How has the COVID-19 pandemic and public health emergency impacted the FDA’s ability to oversee and ensure the safety of infant formula? Did you make a remote records request? Would any authorities have enabled more effective FDA oversight and facilitated the FDA’s ability to meet its obligations?
9. We are concerned about the shortages of infant formula resulting from the recall. What types of information does the FDA collect from infant formula manufacturers regarding disruptions in manufacturing or other supply chain issues that could lead to shortages? Does the FDA have the necessary authority it needs to proactively take steps to prevent or mitigate potential shortages of infant formula?

Your response to these questions is requested by April 29, 2022. Please contact Sara Maskornick at sara_maskornick@help.senate.gov with any questions.

We stand ready to assist the FDA to help protect our most vulnerable population—infants and newborns—from illness or death as a result of ingesting contaminated formula.

Sincerely,



Robert P. Casey, Jr.
United States Senator



Sherrod Brown
United States Senator

⁷ <https://datadashboard.fda.gov/ora/firmprofile.htm?FEI=1815692>