



Congress of the United States
House of Representatives

May 11, 2022

The Honorable Robert Califf, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10902 New Hampshire Ave
Silver Spring, MD 20993

The Honorable Tom Vilsack
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Avenue, SW
Washington, DC, 20250

Dear Commissioner Califf and Secretary Vilsack:

I write to express concerns regarding the extreme shortage of infant formula across the country and the Food and Drug Administration's (FDA's) and United States Department of Agriculture's (USDA's) roles in helping find solutions. It is the responsibility of your administrations to protect infant health and ensure access to safe formula. I am deeply concerned with the apparent lack of an effective strategy to mitigate shortages like the one we are experiencing that risks the lives of infants across the country.

To date, there have been four adverse events and two deaths allegedly associated with Abbott Nutrition powdered infant formulas from its Sturgis, Michigan, facility.¹ In both instances of death, *Cronobacter sakazakii* infection may have contributed to the cause of death, given that the bacteria were found in the facility during the course of a January 2022 – March 2022 inspection.² Prior to this, documentation from FDA has shown instances of potential contamination from facilities or personnel in September 2021.³ These observations are alarming given the health risk posed to some of our nation's most vulnerable.

While I appreciate FDA's current efforts to lower the risk of ingesting contaminated formula, I believe FDA dropped the ball given these concerns date back to 2021. This possible negligence has directly put infants in harm's way.

The product recall and near-shutdown of the Sturgis facility has impacted availability of infant formula and significantly driven up the price. Twenty-six states, including my home state of South Dakota which has an out-of-stock rate of over 50%, are struggling with supply.⁵ By comparison, the out-of-stock rate for infant formula was between 2% and 8% in the first half of 2021 – as of April 2022 it is up to 40% nationwide, according to Datasembly. The FDA needs a robust contingency plan in place to prevent these shortages from happening.

Our government should do everything in its power to prevent a repeat of this crisis. I respectfully request a response to the following questions:

¹<https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022>

²<https://www.fda.gov/media/157073/download>

³<https://www.fda.gov/media/156747/download>


⁵<https://www.cnn.com/2022/05/08/business/baby-formula-shortage/index.html>

1. Please provide a comprehensive update on the investigation of *Cronobacter* infections found in powdered infant formula, an estimated timeline to completion, efforts by FDA to coordinate with other federal agencies, including the USDA, and any authorities that may be necessary to help relieve the formula shortage.
2. FDA received the first infant consumer complaint on September 20, 2021. Were on-the-ground investigators notified of this complaint before the conclusion of the September 20, 2021 – September 24, 2021 inspection period?
3. Between September 24, 2021 and December 18, 2021, FDA received three additional consumer complaints. But a follow-up facility inspection did not begin until January 31, 2022. Why was there a 44-day delay to initiate this inspection?
 - a. Was this inspection regularly scheduled, or was it initiated due to consumer complaints being filed?
 - b. On average, what is the amount of time it takes to review and subsequently investigate a complaint?
4. On February 17, 2022, Abbott Nutrition proactively and voluntarily recalled powdered infant formula products following these consumer complaints being filed. On February 28, 2022, Abbott then expanded its product recall.
 - a. Was FDA notified of this recall prior to its public release? If so, when was FDA notified?
 - b. Did FDA possess data on how much product was being recalled in relation to total supply of infant formula product?
 - c. Following Abbott Nutrition's product recall, did FDA account for a potential product supply shortage? If so, what steps did it take to mitigate a potential shortage?
5. Section 412(c)(1) and 412(d)(1) of the Federal Food, Drug, and Cosmetic Act require companies manufacturing or distributing new infant formula to register with the FDA 90 days before marketing said formula.
 - a. On average, how many new infant formula submissions does FDA receive in one year?
 - b. What percent of submissions come from new market entrants?
 - c. On average, how long does FDA's review of a new infant formula take?
6. Consumers who are supported by the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) can be especially affected by infant formula shortages. In this instance, Abbott Nutrition is the sole-source WIC contractor for 23 states and the District of Columbia.
 - a. Are there contingencies in place at USDA that would allow sourcing outside of the WIC contract in times of emergency, such as a product shortage?
 - b. What communications occurred between USDA and FDA regarding impacts of an infant formula shortage on participants of WIC?
 - c. What communications occurred between USDA and FDA regarding securing access of specialty medical formula for participants of WIC?

- d. To what extent is the FDA working with Abbott Nutrition to transition from the release of products on a case-by-case basis back to a sustained release, particularly for infants with certain health conditions?

I respect the difficult job you and your staff have in managing this crisis, but time is of the essence to find solutions. Please provide your responses to this request by May 24, 2022.

Sincerely,

A handwritten signature in black ink that reads "Dusty Johnson". The signature is written in a cursive, slightly slanted style.

Dusty Johnson
Member of Congress