United States Senate
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510–6300

May 16, 2022

The Honorable Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Bob:

I write today out of deep concern that the Food and Drug Administration's (FDA) inaction and complacency has imperiled the food supply of our youngest and most vulnerable Americans. FDA is charged with ensuring the safety of our nation's food supply, including infant formula. Nationwide supplies of infant formula continue to dwindle, with 40% of the nation's baby formula out of stock.[1] FDA failed to act in a timely fashion to secure the infant formula supply chain, resulting in formula shortages across the country and leaving families unable to access infant formula.

While FDA finally acted to become more engaged with infant formula manufacturers to better understand capacity constraints on formula production and expedited its review processes for these products, these actions are too little, too late. Today's news about the possible reopening of a plant in Michigan is welcome, but that may take at least 2 months for any new product to be delivered.[2] Parents across the country are staring at empty shelves and anxiously awaiting the delivery of critical food for their infants, toddlers, and children with serious metabolic conditions.

This didn't happen overnight.

Since 2020, formula supplies have been running low, and the pause in production from one of the four major formula manufacturers have only worsened such supply challenges, making critical formula scarce.[3] This circumstance is particularly dire for consumers and patients that are reliant on amino-acid based formulas. The facility that reportedly produces 75% of the nation's supply of amino-acid based formula has been closed since February 2021. The Centers for Disease Control and Prevention (CDC) have closed its investigation without finding a direct link

[1] https://www.wsj.com/articles/who-made-the-baby-formula-shortage-biden-administration-abbott-tariffs-nestle-11652480538.
[2] https://www.cnbc.com/2022/05/16/abbott-reaches-agreement-with-fda-to-reopen-baby-formula-plant-to-ease-nationwide-shortage.html
[3] https://time.com/6175211/baby-formula-shortage/.

from this facility to the cronabacter sakazakii infections in children. While multiple inspections have been conducted by FDA, the manufacturing line for these critical foods remains shuttered.[4]

I am particularly concerned to learn that FDA had knowledge about supply challenges, yet did not take decisive action to prevent shortages of this critical food source. While families scramble to find infant formula, the FDA must be held to account for its role in this crisis.

For these reasons, I request a response to the questions below by May 20, 2022:

1. Infant formula shortages began in 2020 and increased sharply in July of 2021.[5] What specific actions did FDA take in the Fall of 2021 to mitigate the shortage of infant formula and specialty formulas?

2. When did FDA first learn of potential risks of shortages to the infant formula supply?

3. What are the specific dates on which the agency became aware of challenges with the manufacturing of infant formula? Please provide each instance by date and facility. How soon did FDA follow up with each facility experiencing manufacturing challenges and what were the actions FDA has taken to facilitate mitigating the aforementioned challenges?

4. What does FDA use to determine that a product is a critical medical food? How does this status impact FDA's work on inspections and review of product submissions?

5. What are the specific reasons that the manufacturing lines for amino acid and other formulas remain down? What is preventing the plant in Sturgis, Michigan from resuming operation? How soon does FDA anticipate this facility reopening and resuming production?

6. What are the specific actions FDA is taking in their efforts to work with the other suppliers of infant formula? Are there suppliers with additional manufacturing capacity that could scale up to help meet the current demand for infant formula? If so, what are the actions FDA is taking to support such manufacturing scale up?

7. Are there alternative products appropriate for purposes of substitutions to the formula products in shortage? If so, what are the actions FDA is taking to fast track any alternative products or appropriate substitutions?

8. How many submissions for new infant formulas and new infant formula manufacturers are currently under review at the FDA?

    a. How long has each submission been under review?

[4] https://www.cdc.gov/cronobacter/outbreaks/infant-formula.html.
[5] https://www.cnn.com/2022/05/08/business/baby-formula-shortage/index.html.

b. What is FDA's plan, in calendar days, to take action on each of these submissions?

9. What are FDA's restrictions on the import of infant formula from overseas?
   a. How is FDA working to facilitate the importation of overseas product?

   b. Can the FDA issue temporary waivers of labeling requirements for overseas products? When will those waivers be issued?

10. What are the regulatory differences related to safety requirements regarding infant formula manufactured and available in countries overseas, namely the United Kingdom, Australia, New Zealand, Japan, Israel, Switzerland, South Africa, the European Union, and the European Economic Zone? What are the regulatory differences, including safety, for formula products manufactured and available in Mexico, Chile, Ireland, and the Netherlands?

11. What are the steps FDA is taking to prioritize getting new domestic products on shelves?

12. How is FDA working with other federal agencies to alleviate the current infant formula shortages?

13. What are remaining barriers to relief of the U.S. shortage of infant and specialty formulas?

Thank you for your time and attention to a matter so critical to American families. I look forward to your timely response.

Sincerely,

Richard Burr