RICK SCOTT
FLORIDA

United States Senate

ARMED SERVICES
HOMELAND SECURITY
BUDGET
SPECIAL COMMITTEE
ON AGING

January 10, 2024

The Honorable Robert M. Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Dear Commissioner Califf:

The Food and Drug Administration (FDA) plays an important role in safeguarding our food and drug supply chain. I write regarding the urgent shortage of baby formula facing mothers and families.

In December, the FDA and Reckitt Benckiser's Mead Johnson Nutrition announced a voluntary recall of their hypoallergenic baby formula due to potential contamination by *Cronobacter sakazakii*, also known as Salmonella Newport.[1] This recall affects over 675,000 cans of baby formula under the brands Enfamil and Nutramigen that were manufactured outside of the United States.

The last time that the FDA issued a recall due to *Cronobacter sakazakii* contamination, it failed to move swiftly to ensure that the market had an adequate supply of baby formula. This created unnecessary shortages, which the FDA later would attempt to mitigate by allowing imports of additional baby formula supply. The FDA cannot repeat its past mistakes.

There are more than 200,000 births in Florida each year and formula is needed to provide critical nutrition for many of those children. Given the importance of baby formula to the well-being of children and families and the need for the FDA to act quickly to ensure families have the food they need to feed their children, please answer the following questions:

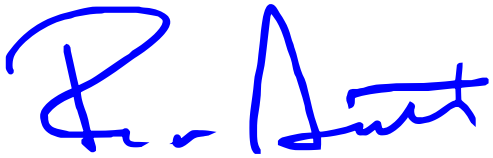
- What is the FDA doing to help get the contaminated facility operating safely and fully back online?
- When does the FDA estimate that the contaminated facility will be running again and when will infant formula supply return to normal levels?

[1] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/reckittmead-johnson-nutrition-voluntarily-recalls-select-batches-nutramigen-hypoallergenic-infant

- How long did it take for the FDA to determine a course of action after it first learned of the bacterial contamination?
- What is the FDA doing to work with other infant formula companies to increase the amount of hypoallergenic formula available in the U.S. marketplace?
- What other countries would be affected by this recall? What is the FDA doing to assist those countries impacted by the recall of the contaminated infant formula?
- Has the FDA established an Incident Management Group to address this shortage?

I look forward to your prompt response so that the youngest and most vulnerable among us have access to the nutrition that they need, and I urge the FDA to take swift and decisive action to solve this growing supply shortage.

Sincerely,



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