RICK SCOTT
FLORIDA

United States Senate

ARMED SERVICES
HOMELAND SECURITY
COMMERCE, SCIENCE, AND TRANSPORTATION
BUDGET
SPECIAL COMMITTEE ON AGING

May 11, 2022

The Honorable Robert M. Califf, M.D.
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 February, FDA and Abbott Nutrition announced a voluntary recall of Similac, Alimentum and EleCare baby formula manufactured in the same Sturgis, Michigan facility due to potential contamination by *Cronobacter sakazakii*, also known as Salmonella Newport. In response, the facility's production came to a stop, affecting around 25% of the baby formula supply in the United States. Considering that baby formula shortages were already afflicting families across the nation, the contamination and recall could not have come at a worse time.

Since the recall started, the supply of baby formula has decreased while demand for baby formula has remained consistent. This shortage of vital nutrition has even impacted a majority of states' Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) because Abbot has been their exclusive supplier.[1] Now, it is estimated that about 40% of store shelves are out of stock of baby formula.[2]

The cause of the current shortage is especially infuriating given prior warning signs. In 2019, the FDA inspected the facility and noted issues dealing with "clean and sanitary conditions," not washing soiled and containment hands before working with formula,[3] and the facility's lack of adequate testing of samples.[4] Furthermore, in

[1] https://www.nwica.org/blog/wic-providers-respond-to-abbott-recall-of-powder-infant-formula-similac-alimentum-elecare
[2] https://www.axios.com/2022/05/06/baby-formula-shortage-abbott-recall
[3] https://www.fda.gov/media/156747/download
[4] https://www.fda.gov/media/156748/download

October 2021, a former employee at the plant sent a report to the FDA outlining concerns about the Sturgis plant's dangerous practices.[5] Despite these reports, the facility continued to operate until four children were hospitalized, and two tragically died.

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 the questions:

- What is the FDA doing to help get the Michigan facility operating safely and fully back online?
- When does the FDA estimate the Sturgis facility will be running again and infant formula supply return to normal levels?
- How long did it take for the FDA to determine a course of action after it first received the whistleblower complaint?
- Why did the FDA wait until February 2022 before finally noting the facility lacked a system to protect from the "presence of microorganisms in the formula or in the processing environment?"[6]
- Has Abbott or any other infant formula manufacturer asked the FDA to inspect an overseas facility to allow for increased US supply? How long would it take the FDA to inspect and approve such a facility?
- What is the FDA doing to work with other infant formula companies to increase the amount of formula available in the U.S. marketplace?
- What is the FDA doing to assist other countries impacted by the recall of U.S. contaminated infant formula?[7]
- How long did it take the FDA to establish the Incident Management Group to address this shortage?

[5] https://www.scribd.com/document/572168183/Redacted-Confidential-Disclosure-Re-Abbott-Laboratories-10-19-2021-Redacted-1-1#from_embed
[6] https://www.fda.gov/media/157073/download
[7] Australia, Bahrain, Barbados, Bermuda, Canada, Chile, China, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, Guam, Guatemala, Hong Kong, India, Indonesia, Israel, Jordan, Kuwait, Lebanon, Malaysia, Mexico, New Zealand, Oman, Peru, Puerto Rico, Qatar, Saudi Arabia, Singapore, South Africa, Sudan, Taiwan, Thailand, United Arab Emirates, United Kingdom, and Vietnam ANI South.

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 urge the FDA to take swift and decisive actions to solve this growing supply shortage.

Sincerely,

Rick Scott
United States Senator