

United States Senate

WASHINGTON, DC 20510

September 26, 2023

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

Dear Commissioner Califf:

As the Food and Drug Administration (FDA) works with U.S. infant formula manufacturers to make much-needed improvements to aging factories, we write to you today to call on the FDA to ensure that production levels for domestic infant formula remains constant, and that store shelves continue to be stocked.

It is imperative that we continue to address the nation's infant formula crisis by meaningfully improving the quality and safety of the U.S. infant formula factory network in order to ensure the health and safety of American infants. As a response to the shortage in 2022, Congress passed several laws directing the FDA to enhance its oversight of the domestic infant formula market. We applaud the agency's work to implement these laws, including increasing inspections and directing companies to make much-needed improvements to factory conditions that resulted in the shortage.

Infant formula is the sole source of nutrition for many infants, and it is critical that the FDA incorporate lessons learned from the 2022 shortage to implement further improvements and ensure stable domestic production levels of infant formula.

As we head toward the end of Fiscal Year 2023, we write to request the following information:

- What strategies has the FDA put in place—or will be putting in place—to ensure that infant formula production numbers remain stable as factory improvements are made?
- Has the FDA been alerted to potential shortfalls in production by any domestic infant formula manufacturers due to manufacturing enhancements required by the new regulations?
- What processes has the FDA put in place to ensure that the agency is made aware of production slowdowns due to product shortages?
- How is the FDA engaging with infant formula manufacturers about ways to increase production to compensate for shortfalls?
- What actions will FDA take to ensure expeditious review of any new or increased domestic manufacturing options, while ensuring the additional safeguards are being met?
- If there is a government shutdown, can you ensure there will be no delay or stand-still of any FDA approvals that will impact the availability of infant formula?

United States Senate

WASHINGTON, DC 20510

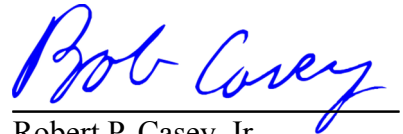
- Are there any domestic infant formula factories in operation that meet the new guidelines?

We request your prompt attention and response to these questions. Please contact Kimberly Lattimore (Kimberly_Lattimore@brown.senate.gov) and Sara Maskornick (sara_maskornick@help.senate.gov) with any further questions.

Sincerely,



Sherrod Brown
United States Senator



Robert P. Casey, Jr.
United States Senator



Martin Heinrich
United States Senator