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United States Senate

COMMITTEE ON APPROPRIATIONS

WASHINGTON, DC 20510-6025

<https://appropriations.senate.gov>

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May 18, 2022

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

As Chair and Ranking Member of the Senate Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Subcommittee, we write to express our deep concerns with the current nationwide infant formula supply shortage. We urge your Agency to take all necessary steps to ensure access to this critical product, now and going forward.

As you know, many families rely on formula to nourish their children, and with many store shelves across the country empty, the current situation has caused unnecessary strain on mothers, fathers, and caregivers. While we appreciate the steps currently being taken by the Food and Drug Administration (FDA), we are concerned that the Agency did not take these actions sooner, and we believe that more must be done to safely alleviate the shortage as quickly as possible. Earlier intervention from the FDA to enhance supply chains, in part by utilizing the authorities announced this week, would have mitigated the impact of the loss of a major manufacturing facility and prevented this crisis.

Through our roles on the Ag-FDA Appropriations Subcommittee, we request that the Agency provide the following information:

- A detailed timeline of the FDA's inspection of the Abbott facility in Sturgis, MI, including dates of inspection and details of problems encountered at the facility by FDA inspectors.
- A full explanation of the Agency's efforts to ensure that all imported formula meets the same high standards of safety and nutrition required by the FDA of U.S. manufacturers. This should include information as to whether there is manufacturing equivalency in overseas facilities and details regarding how the FDA will guarantee these products are safe without in person inspections.
- A complete explanation of actions taken by the FDA to date, and recommendations on how to immediately increase access to infant formula as well as bolster the supply chain.
- A detailed explanation of actions taken to date and recommendations on how the FDA can work to prevent a similar crisis from occurring in the future.

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We recognize that the pandemic has placed tremendous strain on the FDA. However, families cannot wait weeks for the supply chain to resolve itself, and the FDA must act expeditiously to resolve the current infant formula shortage. As Chair and Ranking Member of the Ag-FDA Subcommittee, we are committed to working with you to ensure that the FDA is meeting its mission of protecting public health by ensuring the safety, efficacy, and security of our food and drug supply chain. This shortage is unacceptable to American families, and we must work together to ensure that nothing like this happens in the future. We look forward to your timely response.

Sincerely,

Handwritten signature of Tammy Baldwin in blue ink.

Senator Tammy Baldwin
Chair

Handwritten signature of John Hoeven in blue ink.

Senator John Hoeven
Ranking Member