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May 19, 2022

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

Dear Commissioner Califf,

Thank you for your testimony this morning before the House Committee on Appropriations Subcommittee on Agriculture on the nation's ongoing infant formula supply shortage and other critical issues facing the Food and Drug Administration (FDA). As FDA works to ensure safe and reliable access to formula, I urge to you to ensure that inspections of U.S. infant formula manufacturing facilities are carried out on a safe and timely basis during future public health emergencies or any other period in which other FDA inspections are postponed.

As we have seen in recent weeks, access to safe and affordable infant formula is not optional for American families. Ensuring continuity of inspections is essential in preventing unconscionable and dangerous situations in which parents are unable to find the nutrition their babies need to survive and thrive.

As you know, a whistleblower report shared with House Appropriations Committee Chair Rosa DeLauro included disturbing allegations about wrongdoing at the Sturgis facility, such as releasing untested infant formula, falsifying records, and maintaining lax cleaning practices.[1] This report was allegedly submitted to FDA on October 20, 2021, but FDA did not inspect the plant in person until January 31, 2022.[2]

Within this timeframe – on December 29, 2021 – FDA temporarily postponed certain in-person inspections due to the spread of the omicron variant, but continued to conduct mission-critical work.[3] According to the agency's *Resiliency Roadmap for FDA Inspectional Oversight*, the four factors determining mission-critical inspections are whether a product (1) received breakthrough therapy or regenerative medicine advanced therapy designation; (2) is used to treat a serious disease or medical condition and there is no substitute; (3) requires follow-up due to recall, or there is evidence of serious adverse events or outbreaks of a foodborne illness; or (4) is related to FDA's COVID-19 response.[4]

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[1] Representative Rosa DeLauro: *DeLauro Shares Whistleblower Report, Contaminated Infant Formula Led to Hospitalizations and Deaths*. April 28, 2022.
[2] Ibid.
[3] U.S. Food and Drug Administration: *FDA Roundup: January 4, 2022*. January 4, 2022.
[4] U.S. Food and Drug Administration: *Resiliency Roadmap for FDA Inspectional Oversight*. May 2021.

From your testimony in today's hearing, however, it is clear that this *Roadmap* does not provide sufficient clarity as to whether FDA considered powdered infant formula from the Sturgis facility – and the specialty and metabolic formula produced at the Sturgis facility in particular – to be a product that meets the threshold for mission-critical inspections. Therefore, I respectfully request that you provide a final answer to this question in writing by June 2, 2022. Please also provide guidance as to whether FDA has determined if infant formula produced at other U.S. facilities – including non-specialty formula products – meet the agency's threshold for mission-critical inspections. Lastly, please provide details on the steps FDA is taking to ensure future inspections of infant formula manufacturing facilities are carried out on a safe and timely basis during public health emergencies or any other period in which some inspections are postponed.

Please do not hesitate to reach out to my office if you or your staff have any questions about this priority. Thank you for your prompt attention to this urgent issue. I look forward to working together to ensure a safe and reliable supply of infant formula for families across America.

Sincerely,