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February 28, 2022

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

Dear Commissioner Califf,

I write to you today with grave concern regarding events that led to the Food and Drug Administration (FDA) issuing a sweeping recall of Similac, Alimentum, and EleCare powdered infant formulas. On February 17, 2022, the FDA issued a warning and recalled the formulas following multiple consumer reports of Cronobacter sakazakii and Salmonella Newport infections.[1] This recall occurred months after the Minnesota Department of Health reported initial cases to both the FDA and the Centers for Disease Control and Prevention (CDC).[2]

Allowing months to pass while infants are hospitalized places the health and welfare of our nation's most vulnerable population at severe risk. This is unacceptable. As a result of this sweeping recall, children have been put to bed hungry while parents attempt to identify alternative formulas that are often difficult to procure.[3] This impossible situation for parents may have been largely averted had the FDA acted swiftly upon initial reports of illness.

In the past, the FDA's food recall process has experienced problems in ensuring the safety of the U.S. food supply. A 2017 Department of Health and Human Services Office of Inspector General (OIG) report identified deficiencies in FDA's oversight of recall initiation, monitoring of recalls, and recall of data collection. The report stipulated, "recalls were not always initiated promptly because FDA does not have adequate procedures to ensure that firms take prompt and effective action in initiating voluntary food recalls."[4]

The 2021 publication of the OIG's Top Unimplemented Recommendations indicates that, while the FDA has taken significant steps to address safety concerns in the food system, there are still

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[1] Food and Drug Administration, *FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula,* https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022

[2] Politico, *FDA learned of suspected infant formula illness four months before recall,* https://www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226

[3] ABC 7 News, *Parents put kids to bed hungry after Abbott Nutrition formula recall, FDA investigation* https://wjla.com/news/local/elizabeth-coco-claire-rowan-parents-put-kids-to-bed-hungry-after-abbott-nutrition-formula-recall-fda-investigation-elecare

[4] Department of Health and Human Services Office of the Inspector General, *The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply* https://oig.hhs.gov/oas/reports/region1/11601502RIB.pdf

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unimplemented recommendations related to food safety.[5] As the timeline leading to the February 17th recall remains unacceptable, I request the FDA expeditiously provide the status of all unimplemented recommendations from the 2017 OIG report and any other similar reports regarding the FDA's responsibility to ensure an effective and timely process related to food facility inspections and food recalls. Additionally, I request responses to the following questions:

1) When was the FDA first informed of an illness linked to formula produced at Abbott Nutrition's Sturgis, Michigan facility?

2) When was the FDA made aware of all other additional reports of Cronobacter sakazakii and Salmonella Newport infections?

3) Did the FDA find records indicating that Abbott Nutrition had found bacteria in their Sturgis facility prior to the FDA inspection, and if so, did the company report such findings to the FDA in a timely manner?

4) Why did an FDA inspection of Abbott Nutrition's Sturgis, Michigan facility not occur until January 31, 2022, presumably months after the first report was received?

5) In its recall notice, Abbott Nutrition found evidence of Cronobacter sakazakii in its facility but did not find this bacterium in the product itself.[6] The FDA's review of the firm's internal response indicated Abbott destroyed product due to the presence of Cronobacter sakazakii.[7] Please explain this discrepancy.

Thank you for your prompt consideration of this matter.

Sincerely,

Elise M. Stefanik
Member of Congress

CC: The Honorable Rochelle P. Walensky, Director of the Centers for Disease Control and Prevention

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[5] Department of Health and Human Services Office of the Inspector General, *OIG's Top Unimplemented Recommendations: Solutions to Reduce Fraud, Waste, and Abuse in HHS Programs*https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2021.pdf

[6] Abbott, *Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant* https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant?utm_medium=email&utm_source=govdelivery

[7] Food and Drug Administration, *FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula,* https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022