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HOUSE OF REPRESENTATIVES

ROSA L. DELAURO

3RD DISTRICT, CONNECTICUT

March 3, 2022

The Honorable Christi A. Grimm
Inspector General
Office of the Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Grimm:

I write to seek your assistance in investigating whether the Food and Drug Administration (FDA) took prompt, appropriate, and effective action leading up to the recent recall involving powdered infant formula produced by Abbott Nutrition's Sturgis, Michigan plant. Based on reports, I am concerned the agency acted too slowly in pulling potentially dangerous infant formula off store shelves, which may have resulted in additional illnesses and death.

Abbott announced a recall of several of its powdered infant formulas on February 17 after multiple consumer complaints of infant illnesses related to *Cronobacter sakazakii* and *Salmonella* Newport infections. In their announcement, Abbott admitted that evidence of *Cronobacter sakazakii* was found in their facility.

According to the FDA, the agency first learned of the potential link between a case of *Cronobacter sakazakii*, a rare and deadly foodborne pathogen, and powdered infant formula manufactured by Abbott in September 2021. Near the same time, the agency inspected the same plant where this formula was made and uncovered numerous violations of regulations that are intended to prevent this type of contamination. Alarming, the FDA had also inspected the facility two years prior and uncovered similar issues.

Despite the agency's awareness of these violations, public attention to this issue came to light only recently – nearly four months after the potential link was known. The FDA did not warn consumers about these products until another inspection in February 2022 uncovered *cronobacter* in several places in the Abbott facility. Through this inspection, the agency also was able to uncover company records that revealed Abbott had previously destroyed products due to the presence of *Cronobacter sakazakii*. While the company destroyed the product in June 2020, it was not noted in the agency's September 2021 report, and the FDA has yet to explain why.

This February's inspection was prompted after reports of three illnesses and one death related to *Cronobacter sakazakii* and *Salmonella* Newport. The delay between the September inspection and the recall raises serious questions about the FDA's ability to adequately regulate the infant

formula industry. It seems evident that the FDA could have acted sooner to prevent additional illnesses and deaths after the initial inspection.

As such, I request that you investigate whether the FDA's inspection process and regulatory actions addressed this health hazard in an effective and timely manner. As part of this review, I encourage your office to focus on the following central questions:

- Why did it take several months and additional illnesses for the FDA to return to the plant for a follow-up inspection?
- Why were the company records showing destroyed products in June 2020 omitted from the FDA's September 2021 inspection report?
- Abbott is required to maintain production and testing records of each batch of infant formula and must provide those records to the FDA upon request. Did the agency request these records during the September 2021 inspection? If not, what is the agency's justification for failing to do so?
- Two years prior to the September 2021 inspection, the FDA found that the Abbott facility failed to test a representative sample for *Salmonella* at the final stage of the production cycle. Did the agency follow-up on this issue after that inspection?
- What presence does the FDA now have at the Abbott facility following the February 2022 inspection, and what steps are they taking to ensure the infant formula manufactured at this facility is now safe?
- Does the FDA intend to conduct more frequent inspections of the Abbott facility going forward?
- Did any of the FDA inspections include a significant review of the Abbott Hazard Analysis and Critical Control Points (HACCP) plans from past incidents in order to determine its overall effectiveness, and if they were following correct procedures?
- Will the FDA start conducting its own testing of infant formula to monitor for these dangerous bacteria?
- How is the agency ensuring that all parents and caregivers, including those enrolled in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), have access to safe and affordable infant formula?

Thank you for your attention to this matter and your consideration of this request. Should you have any questions regarding this inquiry please contact Christian Lovell (christian.lovell@mail.house.gov) on my staff at (202) 225-3661.

Sincerely,



ROSA L. DeLAURO
Chair
Committee on Appropriations