United States Senate
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510–6300

February 24, 2022

Robert B. Ford
Chairman of the Board and Chief Executive Officer
Abbott
100 Abbott Park Road
Abbott Park, IL 60064

Dear Mr. Ford:

Last week, Abbott made public that contaminated powder infant formulas manufactured at its Sturgis, Michigan plant have led to multiple infant hospitalizations and one death. While the voluntary recall of three types of formula—Similac, Alimentum, and EleCare—is a critical step to ensuring additional children do not become sickened by these products, we are incredibly concerned that the company received complaints as early as September 2021 but only took public action last week. It is completely unacceptable that manufacturing conditions allowed a contaminated product to reach babies, and that it took months for the company to act to warn parents and caregivers about this danger. We demand answers.

According to press reports, the Minnesota Department of Health began investigating a case of an infant infected with *Cronobacter sakazakii* in September 2021.[1] The baby was hospitalized for 22 days. The investigation revealed the infant had been fed with formula produced at Abbott's Sturgis facility. The Minnesota Department of Health shared this information with the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) at the time. Abbott also confirmed it received a complaint the same month.

Abbott and FDA received additional complaints of infant illness in the subsequent months. FDA has now confirmed four complaints from Minnesota, Ohio, and Texas of *Cronobacter sakazakii* and one report of *Salmonella* Newport infection from products manufactured at the facility.[2] All four infants were hospitalized, and one infant with *Cronobacter* died.

[1] https://www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226
[2] https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022

FDA began a facility inspection on January 31, 2022 and found *Cronobacter sakazakii* in several samples taken at the plant.[3] The inspectors also identified records showing additional evidence of bacteria at the plant and previous destruction of contaminated product. On February 17, 2022, Abbott initiated a voluntary recall of powder formulas manufactured under the Similac, Alimentum, and EleCare labels at the Sturgis plant.[4] The company has not yet identified how many units are being recalled or where they might have been shipped, but FDA identified 36 countries and territories where the recalled products were distributed.[5]

Formula is a critical source of nutrition for newborns and infants. It is particularly disappointing that you would describe the past year as "outstanding" for Abbott when there are such serious outstanding safety concerns. [6] We want to ensure that no corners are being cut when it comes to infant and newborn safety. We demand assurances that your company is taking every effort to work with its state, federal, and global partners to protect any additional children from illness and to ensure parents and caregivers have the information they need—and we remain deeply troubled that this highly vulnerable population was ever placed at risk.

Please provide the following information and documents by no later than March 10, 2022:

1. All internal documents and communications, including emails, related to consumer complaints of contamination in powder infant formula manufactured at the Sturgis, Michigan plant from 2017 to present. This should include documents and communications surrounding the September 2021 report of *Cronobacter sakazakii* infection in Minnesota.

2. All internal documents and communications, including emails, related to monitoring of environmental contamination with *Cronobacter sakazakii*, *Salmonella* Newport, or any other bacteria harmful to human health at the Sturgis, Michigan plant from 2017 to present.

3. All internal documents and communications, including emails, related to the destruction of product due to the presence of *Cronobacter sakazakii*, *Salmonella* Newport, or any other bacteria harmful to human health at the Sturgis, Michigan plant from 2017 to present.

4. All documentation from audits, investigations, and reviews conducted by Abbott or outside consultants or entities related to manufacturing practices and conditions at the Sturgis, Michigan plant from 2017 to present.

[3] https://www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226
[4] https://abbott.mediaroom.com/2022-02-17-Abbott-Voluntarily-Recalls-Powder-Formulas-Manufactured-at-One-Plant
[5] https://www.washingtonpost.com/business/2022/02/18/fda-baby-formula-abbott/; https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022
[6] https://abbott.mediaroom.com/2022-01-26-Abbott-Reports-Strong-Fourth-Quarter-2021-Results-Issues-2022-Forecast

Thank you in advance for your attention to this matter. If you have any questions or would like to discuss compliance with this request, please contact Elizabeth Letter with Senator Murray's staff at Elizabeth_Letter@help.senate.gov or Sara Maskornick with Senator Casey's staff at Sara_Maskornick@help.senate.gov.

Sincerely,

Patty Murray
Chair
U.S. Senate Committee on Health, Education, Labor and Pensions

Robert P. Casey Jr.
Chairman
Subcommittee on Children and Families
U.S. Senate Committee on Health, Education, Labor and Pensions