May 13, 2022

Dear Customer,

Thank you for all you are doing for your patients. As you are navigating conversations with patients, parents, and caregivers we want to provide you with some additional information regarding findings of the investigation and restarting operations at our Sturgis, MI facility, the availability of product, and information about the quality and safety of products produced at other facilities.

**Findings of the Investigation and Restarting Sturgis**

The February voluntary recall involved four complaints of *Cronobacter sakazakii* — a common environmental bacteria — in infants who consumed infant formulas produced in this plant. Two infants became sick; two tragically passed away.

The facts about what was learned about the cases of *Cronobacter* have not been widely communicated. After a thorough review of all available data, there is no evidence to link our formulas to these infant illnesses.

It's important to know:

- Abbott conducts microbiological testing on products prior to distribution and no Abbott formula distributed to consumers tested positive for *Cronobacter sakazakii* or *Salmonella*.
- All finished product testing by Abbott and the FDA during the inspection of the facility came back negative for *Cronobacter* and/or *Salmonella*. No *Salmonella* was found at the Sturgis facility.
- The *Cronobacter sakazakii* that was found in environmental testing during the investigation was in non-product contact areas of the facility and has not been linked to any known infant illness. Specifically:
  - Genetic sequencing on the two available samples from ill infants did not match strains of *Cronobacter* in our plant. Samples from ill infants did not match each other, meaning there was no connection between the two cases.
  - In all four cases, the state, FDA, and/or CDC tested samples of the Abbott formula that was used by the child. In all four cases, all unopened containers tested negative.
  - Open containers from the homes of the infants were also tested in three of the four cases; two of the three tested negative. The one positive was from an open container from the home of the infant, and it tested positive for two different strains of *Cronobacter sakazakii*, one of which matched the strain that caused the infant’s infection, and the other matched a strain found on a bottle of distilled water in the home used to mix the formula. Again, neither strain matched strains found in our plant.
  - The infants consumed four different types of our formula made over the course of nearly a year and the illnesses took place over several months in three different states.

The FDA concluded its inspection with a 483 letter to Abbott on March 18. This is a list of observations that point out where Abbott did not follow our processes and where we can improve our systems and protocols.
We take this very seriously and we responded to the 483 on April 8. Even before our formal response, we had begun working to address these issues, implement improvements and take corrective action. Some of these actions have included reviewing and updating education, training and safety procedures for both employees and visitors, as well as updating our protocols regarding water and cleaning and maintenance procedures at the facility. We immediately implemented corrections to address the items the FDA raised in the 483. We’ve also been making upgrades to the plant, including installing nonporous, easily cleanable and sanitary floors.

Subject to FDA approval, we would begin production of EleCare, Alimentum and metabolic formulas first and then begin production of Similac and other formulas. From the time we restart the site, it will take six to eight weeks before product is available on shelves.

**Product Availability**

We know the recall has worsened an already existing industry-wide infant formula shortage in the U.S. and we've been seeing and hearing the stress and despair of parents who are facing empty shelves. We deeply regret the situation and understand the urgency of getting formula onto shelves. Getting Sturgis up and running will help alleviate these shortages, especially for specialty powder products.

We are working hard to improve the situation through reprioritization initiatives and partnership with the US FDA and USDA/FNS and WIC Agencies.

- We have increased production of the primary contracted WIC SKU Similac Advance, 12.4 oz powder at our other FDA-registered facilities, and Abbott supply of this product is healthy.
- Liquid products were not impacted by the recall, and we have increased production of liquid infant formula.
  - There is minimal interruption in supply of liquid infant formulas to hospitals to allow for in-patient feeding.
- About a week ago, Abbott began releasing metabolic formulas and Similac PM 60/40 on a case-by-case urgent need basis at FDA’s request.
- As our Sturgis manufacturing facility remains unopened, these powder products remain unavailable: EleCare/EleCare Jr., Similac for Spit Up, Similac Alimentum. Please work with the families’ health care provider to consider alternate solutions.
- PediaSure can and bottle inventory remains variable; please contact us to understand which products are currently available for ordering should you experience an out of stock.

**Quality & Safety of Other Facilities**

As a part of Abbott’s standards, we conduct an assessment across all our manufacturing facilities following inspection observations. We have confidence in our quality systems and stand behind the safety and quality of the Abbott products in the market.

We remain committed to sharing updates with you as we work towards regaining family’s confidence in both the quality and availability of Similac formulas.

Mark Berens

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Abbott Nutrition
For more information about the voluntary recall, visit Similacrecall.com or call our hotline 1-800-986-8540.