



Abbott
3300 Stelzer Rd
Columbus, OH 43219

May 18, 2022

Dear Healthcare Provider:

We announced an agreement to enter into a consent decree with the U.S. FDA related to the Sturgis facility. The agreement does not affect any other Abbott plant or operation. The consent decree lays out a series of necessary steps that must be met before reopening and regarding ongoing management of the plant. Abbott has already initiated many of these conditions as part of its corrective action process.

Our top priority is re-starting production at Sturgis and getting formula to those who need it. We know this is urgent and that our recall worsened the shortage. This agreement supports our ability to get back to serving parents and babies. Once the FDA confirms the initial requirements for start-up have been met, Abbott could restart the site within two weeks. We'll come back online as quickly and safely as possible, starting with specialty products, including EleCare, Alimentum and metabolic formulas, and then beginning production of Similac and other formulas.

Abbott has been around for 130 years because we're trusted to do the right thing. We will work hard to re-earn the trust parents, caregivers and healthcare professionals have placed in our formulas. It's important to know that there is no conclusive evidence to link our formulas to the reported infant illnesses. Specifically:

- CDC concluded its investigation with no findings of a link between Abbott formulas and infant illnesses.
- Abbott conducts microbiological testing on products prior to distribution and no Abbott formula distributed to consumers tested positive for *Cronobacter sakazakii* or *Salmonella*.
- All retained product tested by Abbott and the FDA during the inspection of the facility came back negative for *Cronobacter sakazakii* 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.
- Genetic sequencing on the two available samples from ill infants did not match strains of *Cronobacter sakazakii* in our plant. Available 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 used by 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.

We're committed to supporting our valued customers during this time, and we understand this situation is urgent—getting the Sturgis manufacturing facility up and running will help alleviate this shortage. Thank you for your understanding as we continue to work through this situation.

Mark Berens

A handwritten signature in black ink that reads "Mark A. Berens". The signature is written in a cursive, slightly slanted style.

Division Vice President Pediatric Nutrition Sales

Abbott Nutrition

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