FDA NEWS RELEASE

FDA Warns Consumers Not to Use Certain Powdered Infant Formula Produced in Abbott Nutrition's Facility in Sturgis, Michigan

For Immediate Release:

February 17, 2022

Updates:

August 1, 2022: Certain specialty and metabolic formulas have been tested and released by Abbott Nutrition on a case-by-case basis (/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022). Parents and caregivers of infants receiving this specialty and metabolic formula should not reference the recall product description above, but instead should enter the product lot code found at the bottom of their package by using the "Check Lot Number" feature at the bottom of the company's webpage (https://www.similacrecall.com/us/en/home.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) or by calling Abbott Nutrition at 1-800-881-0876.

On Feb. 28, CDC announced one additional illness of Cronobacter sakazakii with exposure to powdered infant formula produced at Abbott Nutrition's Sturgis, Michigan facility. Cronobacter infection may have been a contributing cause of death for this patient. In total, this investigation includes four reports of Cronobacter sakazakii infections in infants (three from FDA complaints and one from a CDC case finding) and one complaint of a Salmonella Newport infection in an infant. All five (four Cronobacter infections and one Salmonella Newport infection) illnesses resulted in hospitalization and Cronobacter may have contributed to death in two patients.

The most recent patient was reported to have consumed Abbott Nutrition's Similac PM 60/40 product with the lot code 27032K800 prior to Cronobacter sakazakiiI infection. The FDA and CDC informed the firm of these findings and on Feb. 28, 2022, Abbott Nutrition voluntarily recalled Similac PM 60/40 powdered infant formula with the lot code 27032K800. This is a specialty formula for certain infants who would benefit from lowered mineral intake and was not included in the previous recall. At this time, Similac PM 60/40 with lot code 27032K80 (can) / 27032K800 (case) are the only type and lots of this specialty formula being recalled.

On Feb. 17, Abbott announced that the company initiated a voluntary recall (/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant) of potentially affected products, including Similac, Alimentum and EleCare powdered formulas manufactured in its Sturgis, Michigan facility. Products made at this facility can be found across the U.S. and were likely exported to other countries as well. Canadian health officials have also issued a recall warning (https://recalls-rappels.canada.ca/en/alert-recall/certain-abbott-brand-powdered-infant-formula-products-recalled-due-cronobacter) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). Additional recall information is available on the FDA website (/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant). Parents and caregivers can also enter their product lot code on the company's website (https://www.similacrecall.com/us/en/home.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to check if it is part of the recall.

FDA is continuing to investigate and will update this advisory should additional consumer safety information become available: FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula (February 2022) | FDA (/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022).

Español (/news-events/press-announcements/la-fda-advierte-los-consumidores-que-no-usen-ciertas-formulas-infantiles-en-polvo-producidas-de-las)

Today, the U.S. Food and Drug Administration announced it is investigating consumer complaints of *Cronobacter sakazakii* and *Salmonella* Newport infections. All of the cases are reported to have consumed powdered infant formula produced from Abbott Nutrition's Sturgis, Michigan facility. As a result of the ongoing investigation, along with the U.S. Centers for Disease Control and Prevention and state and local partners, the FDA is alerting consumers to avoid purchasing or using certain powdered infant formula products produced at this facility. This is an ongoing investigation, and the firm is working with the FDA to initiate a voluntary recall of the potentially affected product.

The FDA is advising (https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022) consumers not to use Similac, Alimentum, or EleCare powdered infant formulas if:

- the first two digits of the code are 22 through 37; and
- the code on the container contains K8, SH or Z2; and
- the expiration date is 4-1-2022 (APR 2022) or later.

The FDA is investigating complaints of four infant illnesses from three states. All four cases related to these complaints were hospitalized and *Cronobacter* may have contributed to a death in one case. The FDA has initiated an onsite inspection at the facility. Findings to date include several positive *Cronobacter sakazakii* results from environmental samples taken by the FDA and adverse inspectional observations by the FDA investigators. A review of the firm's internal records also indicate environmental contamination with *Cronobacter sakazakii* and the firm's destruction of product due to the presence of *Cronobacter*.

"As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections," said Frank Yiannas, FDA Deputy Commissioner for Food Policy and Response. "We want to reassure the public that we're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible."

Additional Information:

- Products made at the Sturgis, Michigan facility can be found across the U.S. and were likely exported to other countries.
- Products that do not contain the information listed above are not impacted. The FDA advisory (https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022) does not include liquid formula products or any metabolic deficiency nutrition formulas. Consumers should continue to use all products not covered by the advisory.
- To date, this investigation has been associated with four illnesses (three for *Cronobacter* and one for *Salmonella*) spanning the following states: MN, OH and TX. All four cases related to these complaints were hospitalized and *Cronobacter* may have contributed to a death in one case.
- *Cronobacter* (https://www.cdc.gov/cronobacter/infection-and-infants.html) bacteria can cause severe, life-threatening infections (sepsis) or meningitis (an inflammation of the membranes that protect the brain and spine). Symptoms of sepsis and meningitis may include poor feeding, irritability, temperature changes, jaundice (yellow skin and whites of the eyes), grunting breaths and abnormal movements. *Cronobacter* infection may also cause bowel damage and may spread through the blood to other parts of the body.
- Parents and caregivers of infants who have used these products, and are concerned about the health of their child, should contact their child's health care provider. If your child is experiencing any of these symptoms, you should notify your child's healthcare provider and seek medical care for your child immediately.

- *Salmonella* are a group of bacteria that can cause gastrointestinal illness and fever called salmonellosis. Most people with salmonellosis develop diarrhea, fever and abdominal cramps. More severe cases of salmonellosis may include a high fever, aches, headaches, lethargy, a rash, blood in the urine or stool, and in some cases, may become fatal.
- Parents and caregivers should never dilute infant formula and should not make or feed homemade infant formula to infants (https://www.fda.gov/food/alerts-advisories-safety-information/fda-advises-parents-and-caregivers-not-make-or-feed-homemade-infant-formula-infants).
- If your regular formula is not available, contact your child's healthcare provider for recommendations on changing feeding practices.

The FDA is continuing to investigate and will provide additional consumer safety information when it becomes available.

Related Information

- FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula (February 2022) (https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022)
- CDC information on Cronobacter and infant formula (https://www.cdc.gov/cronobacter/infection-and-infants.html)
- Salmonella Homepage | CDC (https://www.cdc.gov/salmonella/index.html)
- Who to Contact (https://www.fda.gov/food/recalls-outbreaks-emergencies/outbreaks-foodborne-illness#:~:text=Who to Contact,their symptoms and receive care)

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