

Title: Recall Expanded in Infant Botulism Outbreak Linked to Infant Formula, November 2025

• Key Points

- CDC and public health officials in several states, the Infant Botulism Treatment and Prevention Program, and FDA are investigating a multistate outbreak of infant botulism linked to recalled infant formula.
- The recall has been expanded to include any ByHeart Whole Nutrition infant formula.
- Infant botulism happens when swallowed spores from a type of bacteria called *Clostridium botulinum* infects a baby's large intestine and make toxin in it. Infant botulism often starts with constipation but is usually first noticed as difficulty feeding (sucking and swallowing), a weak and altered cry, and loss of muscle tone.
- There have been 15 cases of infant botulism linked to this formula nationwide, resulting in 15 hospitalizations and no deaths. There has been 1 case in Oregon.
- The investigation is ongoing and additional information will be shared as it becomes available.

Recalled Food

CDC and FDA are concerned that other lots of ByHeart Whole Nutrition infant formula may be contaminated and are making infants sick with infant botulism. Parents and caregivers have reported feeding infants in this outbreak different lots of ByHeart infant formula that were not included in the company's recall on November 8, 2025. On November 11, 2025, ByHeart Inc. recalled all ByHeart Whole Nutrition infant formula products.

Parents and caregivers are urged to stop using any ByHeart Whole Nutrition infant formula immediately. This includes:

- **All lot numbers**
- **All sizes of cans and single serve sticks**

ByHeart Whole Nutrition Infant Formula is available for sale online and at major retailers nationwide. FDA reports that ByHeart Whole Nutrition Infant Formula makes up an estimated 1% of all infant formula sales in the United States and this outbreak does not create shortage concerns of infant formula for parents and caregivers.

What you should do

- Do not use any ByHeart Whole Nutrition infant formula. This includes formula sold in cans and single serve sticks.
 - If possible, record the lot number and best by date in case your infant becomes ill.
 - If you have leftover ByHeart powdered formula that your infant was fed, keep it stored for at least a month. If your infant develops symptoms of infant botulism, your state health department may want to collect it for testing. If no symptoms appear after a month, throw the leftover formula away.
- Wash items and surfaces that may have touched the recalled formula using hot soapy water or a dishwasher.
- Seek immediate medical care if your infant has consumed ByHeart Whole Nutrition Infant Formula and has any of these symptoms:
 - Poor feeding
 - Loss of head control
 - Difficulty swallowing
 - Decreased facial expression
- Symptoms of infant botulism can take as long as several weeks to develop, so parents should remain vigilant if they used the recalled lots of infant formula.

What businesses should do

- Do not sell or use recalled infant formula.
- Wash and sanitize items and surfaces that may have touched recalled formula.

What clinicians should do

- Initial diagnosis of infant botulism is based on [clinical symptoms](#).
- Consultation with the [Infant Botulism Treatment and Prevention Program](#) is available for suspected cases. If you suspect your infant patient has botulism, immediately call 510-231-7600 for case consultation. Consultation is available 24/7.
- If clinical consultation supports infant botulism, begin treatment as soon as possible. Do not wait for laboratory confirmation.
- Infant botulism is a notifiable disease. All suspected cases must be reported to the state public health department at 971-673-1111.

Symptoms of infant botulism

- Most infants with infant botulism will initially develop constipation, poor feeding, loss of head control, and difficulty swallowing.
- If untreated, infants with infant botulism experience a progressive, flaccid paralysis that can lead to breathing difficulties and require weeks of hospitalization.
- Treatment with BabyBIG® is recommended for all suspected cases of infant botulism.

Resources

[CDC Infant Botulism Outbreak Linked to Infant Formula, November 2025](#)

[FDA Outbreak Investigation of Infant Botulism: Infant Formula \(November 2025\)](#)