

**Alabama Department of Public Health
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
November 17, 2025**

A Multistate Outbreak of Infant Botulism Associated with ByHeart Whole Nutrition Infant Formula

On November 8, 2025, the Centers for Disease Control and Prevention (CDC) and U.S. Food & Drug Administration (FDA) alerted states to an outbreak of infant botulism associated with ByHeart Whole Nutrition infant formula. Initially only two lots of formula were recalled by ByHeart, Inc., but the recall has since been expanded to include all formula products (cans and self-serve packets) made by this brand.

As of November 14, there have been 23 suspected or confirmed cases of infant botulism reported from 13 states. All have been hospitalized and treated with BabyBIG® (Botulism Immune Globulin Intravenous medication). No deaths have been reported. To date, no cases associated with this outbreak have been reported in Alabama, but the Department of Public Health (ADPH) is actively monitoring the situation. Personnel from both ADPH and the Alabama Department of Agriculture & Industries are working diligently to ensure all products have been removed from retailers' shelves across the state.

Parents and caregivers should be instructed to stop using any ByHeart Whole Nutrition infant formula immediately, and wash items and surfaces that may have touched the recalled formula using hot soapy water or a dishwasher. If possible, parents and caregivers should record the lot number and use by date or take a picture of the information which can be found on the bottom of the packaging. They should keep the formula in a safe place and clearly label the product as DO NOT USE. Symptoms of infant botulism can take between 3 and 30 days to develop, so parents and caregivers should remain vigilant if their infant consumed ByHeart Whole Nutrition infant formula. If their child does not develop symptoms after 30 days, parents or caregivers should throw the product away.

Clinical Background

Infant botulism occurs when spores of *Clostridium botulinum*, or related species of bacteria are swallowed. The spores temporarily colonize an infant's large intestine and produces a toxin that blocks the neuromuscular junction by inhibiting the release of acetylcholine.

Initial signs and symptoms of infant botulism often include:

- Constipation
- Difficulty feeding (difficulty sucking or swallowing)
- Loss of head control
- Weak facial expression
- Reduced muscle tone

Without prompt recognition and treatment, descending paralysis may progress and involve the respiratory muscles, potentially leading to life-threatening respiratory failure.

Treatment

If infant botulism is suspected, clinicians should call the [Infant Botulism Treatment and Protection Program \(IBTPP\)](#) immediately at 510-231-7600. Consultation is available 24/7. If clinical consultation supports infant botulism, treatment should begin as soon as possible rather than waiting for laboratory confirmation. Then, clinicians should notify ADPH's Infectious Diseases and Outbreaks Division at 334-206-5971 or 1-800-338-8374.

Testing

All testing for botulism requires pre-approval. If approved, ADPH's Bureau of Clinical Laboratories (BCL) can test for botulinum toxin in food (including formula), serum, and stool, although stool is required to definitively diagnosis infant botulism. Prior to shipment, the clinical or commercial laboratory should contact the BCL at 334-290-6186 to coordinate testing.

Specimen Type and Instructions			
Specimen	Amount	Collection	Storage and Shipment Temperatures
Food	At least ½ cup	Leave food specimens in original container if possible.	Send immediately but call prior to shipment. <ul style="list-style-type: none">• Refrigerate at 2-8°C until shipment.• Ship food separately from clinical samples. Include in shipment label: Biological Substance, Category B UN 3373
Serum	5 mL	Serum: Venipuncture - Collect in SST or Red Top Serum Tube	
Stool	5 g	Stool Collection Guidance	

Recalled Formula

All ByHeart Whole Nutrition infant formula products (cans and self-serve packets) have been recalled. Parents and caregivers should be instructed to stop using any ByHeart Whole Nutrition infant formula immediately. If possible, parents and caregivers should record the lot number and use by date or take a picture of the information which can be found on the bottom of the packaging. They should keep the formula in a safe place and clearly label the product as DO NOT USE. If their child does not develop symptoms after 30 days, parents or caregivers should throw the product away.

ByHeart Whole Nutrition Infant Formula makes up less than 1% of all infant formula sold in the United States and this outbreak does not create shortage concerns of infant formula for parents and caregivers.

Images of recalled product from [FDA website](#):



UPC Codes of recalled products: cans (85004496800) and self-serve packs (85004496802)

Additional Resources

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

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

ByHeart: [ByHeart Whole Nutrition Infant Formula](#)