

Alaska Public Health Alert



ByHeart Whole Nutrition Infant Formula Recall ***Risk of Infant Botulism***

November 13, 2025

All suspected cases of infant botulism must be immediately reported to the Alaska Section of Epidemiology at 907-269-8000 or 800-478-0084 (after hours).

The U.S. Centers for Disease Control (CDC), the California Department of Public Health - Infant Botulism Treatment and Prevention Program, the U.S. Food and Drug Administration (FDA), and public health officials from multiple states are investigating a multistate outbreak of infant botulism associated with ByHeart powdered infant formula.

Since August 2025, 22 suspected or confirmed cases of infant botulism have been identified in 14 states among infants who consumed ByHeart Whole Nutrition Infant Formula. Six cases have been confirmed, and have tested positive for botulinum toxin type A. Affected infants range in age from 16 days to several months. All 15 infants were hospitalized and treated with BabyBIG®, and no deaths have been reported.

There have been no reported cases of infant botulism in Alaska this year.

On November 11, 2025, ByHeart Inc. recalled all ByHeart Whole Nutrition Infant Formula products, including: all lot numbers, all sizes, and single-serve packets.

ByHeart Whole Nutrition Infant Formula was sold online and in major retail stores nationwide, including locations in Alaska. The Alaska Department of Environmental Conservation (DEC) and the Anchorage Health Department (AHD) are working to assure removal of all ByHeart infant formula products from retail shelves in Alaska.

Guidance for Parents and Caregivers

- Stop using any ByHeart Whole Nutrition infant formula immediately, regardless of lot number or size.
 - Record the lot number and “best by” date from any formula on hand.
 - Store any opened or unopened formula securely for 30 days. Clearly label containers “DO NOT USE” and seal the container shut in case testing is needed if your infant develops symptoms of infant botulism. If no symptoms appear after 30 days, throw the formula away.
- Wash items and surfaces that may have touched the formula using hot soapy water or a dishwasher.
- Monitor infants closely for symptoms of infant botulism, which may take up to 30 days after ingestion to appear.
- Seek immediate medical care if your infant consumed ByHeart Whole Nutrition Infant Formula and develops any of the following symptoms:
 - Poor feeding or weak sucking

- Loss of head control
- Weak or diminished facial expression
- Difficulty swallowing or constipation

Guidance for Health Care Providers

Health care providers should maintain heightened clinical suspicion for infant botulism in any infant presenting with compatible symptoms who were fed ByHeart powdered infant formula. Infant botulism differs from foodborne botulism. In infant cases, *Clostridium botulinum* spores are ingested, colonize the intestines, and produce botulinum toxin that enters the blood and affects cholinergic neurons. Progressive symptoms result from ongoing toxin production affecting more neurons.

Treatment is with BabyBIG®, an intravenous immunoglobulin (IVIG) that neutralizes circulating botulinum neurotoxin types A and B. It does not reverse the paralytic effects on neurons that were already affected prior to treatment.

- Diagnosis of infant botulism (patients aged <15 months) is based on [clinical symptoms](#).
- Educate families about the formula recall.
- Educate families how to monitor for signs of infant botulism.
- Infant botulism is not expected to develop >30 days after the last ingestion of formula.
- Testing and treatment are not recommended for asymptomatic infants.
- If infant botulism is suspected, immediately contact the California Department of Health ***Infant Botulism Treatment and Prevention Program***.
 - Phone: 510-231-7600 (24/7); website: <http://www.infantbotulism.org/>
- If clinical consultation supports the diagnosis of infant botulism, administer BabyBIG® promptly – do not wait for laboratory confirmation.
- Immediately report all suspected cases to the Alaska Section of Epidemiology.
 - Phone: 907-269-8000 or 800-478-0084 (after hours).

RESOURCES

- CDC Infant Botulism Outbreak information, <https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html>
- FDA Outbreak Investigation: Infant Botulism—Infant Formula, Nov 2025 — [U.S. Food and Drug Administration](#)
 - [Original recall](#) 11/08/2025, [Updated recall](#) 11/11/2025
- CDC Clinical Overview of Infant Botulism, <https://www.cdc.gov/botulism/hcp/clinical-overview/infant-botulism.html>
- Infant Botulism Treatment and Prevention Program, California Dept. of Health, <https://infantbotulism.org/>