



Public Health

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November 12, 2025

ADVISORY

Infant Botulism and Formula Recall

Multistate outbreak of infant botulism linked to recalled ByHeart infant formula; primary care, ED, and urgent care providers should maintain high suspicion in infants with compatible symptoms and act on evaluation, consultation, treatment, and reporting.

Key Message:

- Two lots of ByHeart Whole Nutrition Infant Formula were voluntarily recalled on November 8, 2025, both labeled “Use by 01 Dec 2026.”:
 - 206VABP/251261P2
 - 206VABP/251131P2
- Thirteen hospitalizations (zero deaths) have been reported across 10 states; investigation and product testing are ongoing.
- Symptoms can develop over several weeks and may include poor feeding, loss of head control, difficulty swallowing, and decreased facial expression in affected infants.
- If infant botulism is suspected, call the Infant Botulism Treatment and Prevention Program (IBTPP) at 510-231-7600 for 24/7 consultation, begin BabyBIG® (botulism immune globulin intravenous, human) as indicated, **do not wait for lab confirmation**, and report suspected cases to Tarrant County Public Health 817-321-5350.

Situational Summary

CDC, FDA, the Infant Botulism Treatment and Prevention Program (IBTPP), and state partners are investigating a multistate outbreak of infant botulism linked to recalled ByHeart Whole Nutrition Infant Formula.

On November 8, 2025, ByHeart initiated a recall of two lots: 206VABP/251261P2 and 206VABP/251131P2 (both “Use by 01 Dec 2026”), with the lot code and “Use by” date printed on the bottom of the can.

As for the latest update, 13 illnesses and 13 hospitalizations with no deaths have been reported in AZ, CA, IL, MN, NJ, OR, PA, RI, TX, and WA, and additional testing and trace-back activities are ongoing.

ByHeart Whole Nutrition Infant Formula lots 206VABP/251261P2 and 206VABP/251131P2 have been voluntarily recalled nationally; caregivers should not use these lots and should discard them, recording the bottom-of-can lot information if available. FDA notes ByHeart Whole Nutrition Infant Formula represents less than an estimated 1% of U.S. formula sales, and supply shortages are not expected due to this recall. Clinics and retailers should not sell or use recalled lots and should clean and sanitize surfaces and items that may have contacted recalled formula.

Note: On November 11, 2025 ByHeart updated its voluntarily recall to all products.

Recommendation

Infant botulism results from intestinal colonization by spores of *Clostridium botulinum* with in-situ toxin production causing bulbar palsies, hypotonia, and symmetric, descending, flaccid paralysis. Common early findings include constipation, poor feeding, weak or altered cry, ptosis, flattened facial expression, diminished suck and gag reflexes, and progressive respiratory difficulty that can lead to arrest. Symptoms may take several weeks to manifest after exposure; vigilance is warranted in infants who consumed the recalled lots.

Initial diagnosis of infant botulism is based on clinical symptoms; consultation is available for suspected cases; if you suspect your infant patient has botulism, immediately call 510-231-7600 for case consultation (available 24/7); if clinical consultation supports infant botulism, begin treatment as soon as possible and do not wait for laboratory confirmation; infant botulism is a notifiable disease and all suspected cases are to be reported to the public health department. Maintain a low threshold to evaluate infants with constipation plus neuromuscular signs (poor feeding, weak cry, hypotonia, or cranial nerve palsies), particularly if they consumed ByHeart recalled lots.

Treatment is BabyBIG® for infants with clinically supported infant botulism, released through IBTPP after consultation. Antitoxin halts progression by neutralizing circulating toxin but does not reverse established paralysis; early administration reduces complications. Supportive care, including airway and feeding support, should be provided in an appropriate inpatient setting given risk of respiratory compromise.

Selected References:

1. <https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html>
2. <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025>
3. <https://www.cdc.gov/botulism/hcp/clinical-overview/infant-botulism.html>
4. <https://www.cdc.gov/botulism/hcp/clinical-overview/index.html>
5. <https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/investigation.html>
6. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/response-broader-fda-investigation-byheart-initiates-voluntary-recall-two-batches-infant-formula>
7. <https://byheart.com/pages/nov-8-an-update-from-our-founders-on-our-voluntary-recall-november-2025>
8. <https://www.infantbotulism.org>
9. <https://infantbotulism.org/contact/index.php>
10. <https://www.infantbotulism.org/physician/obtain.php>
11. <https://www.fda.gov/media/150406/download>
12. <https://www.ncbi.nlm.nih.gov/books/NBK493178/>
13. <https://www.cdc.gov/botulism/outbreaks-investigations/index.html>

	Alert:	Conveys the highest level of importance; warrants immediate action or attention
	Advisory:	Provides important information for a specific incident or situation; may not require immediate action.
	Update:	Provides update information regarding an incident or situation; unlikely to require immediate action.
	Information:	Provides general information that is not necessarily considered to be of an emergent nature.

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