



KENTUCKY HEALTH ALERT

Recall of ByHeart Whole Nutrition Infant Formula due to Potential Risk of Botulism

November 10, 2025

Health officials are investigating a multistate outbreak of infant botulism linked to ByHeart Whole Nutrition Infant Formula, a powdered infant formula that has been recalled. Formula from the batches listed below should not be used. Infants that may have been fed this formula should be monitored for symptoms of botulism.

Affected Products:

ByHeart Whole Nutrition Infant Formula, Milk-Based Powder
(UPC: 5004496800)

- Batch Code: 251261P2 ("Use by: 01 Dec 2026")
- Batch Code: 251131P2 ("Use by: 01 Dec 2026")

The "batch code" and "use by" date are found on the bottom of the can. This product is sold in many retail stores in Kentucky and through online retailers.

Symptoms of Botulism in Infants Include:

- Constipation
- Poor feeding
- Loss of head control
- Difficulty swallowing
- Decreased facial expression
- Ptosis (drooping eyelid)
- Sluggish pupils
- Diminished suck and gag reflexes
- Weak and altered cry
- Respiratory difficulty and possibly respiratory arrest

These symptoms may take several weeks to develop.

Infants who are believed to have consumed ByHeart Whole Nutrition Infant Formula and who have any of these symptoms should receive medical attention immediately. Botulism requires urgent medical care and treatment with a specialized antitoxin.

Background:

The Centers for Disease Control & Prevention (CDC), Food & Drug Administration (FDA) and officials in several states including Kentucky, are investigating a multistate outbreak of infant botulism linked to

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ByHeart Whole Nutrition Infant Formula. As of November 10, 2025, thirteen infants with botulism have been linked to the product, suggesting possible contamination with *Clostridium botulinum*, the bacterium that causes botulism.

Botulism is a rare but serious illness that can cause muscle weakness, breathing difficulties and paralysis. It can be life-threatening, especially for infants. Although the product has not been confirmed as the source of the illnesses, ByHeart, Inc. voluntarily recalled the two batch numbers listed above on November 8, 2025.

Action Steps:

For Clinicians

- Initial diagnosis of infant botulism is based on [clinical symptoms](#).
- 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 immediately by telephone to the local health department in the patient's county of residence and the Kentucky Department for Public Health, Division of Epidemiology & Health Planning at 502-564-3261.**
- Public health investigators may request a sample of the formula for laboratory testing. If the infant's family has not thrown away the formula in question, please ask them to place it in a sealed plastic bag or container and bring it to you. You should label it "DO NOT USE – Possible Foodborne Illness Investigation."
- If you suspect your infant patient has botulism, consultation with the [Infant Botulism Treatment and Prevention Program](#) is available 24/7 at 510-231-7600.

For Caregivers

- Stop using the product immediately: Do not feed your infant formula from the affected batches and record the batch code number if possible.
- Throw away ByHeart Whole Nutrition Infant Formula with batch code 251261P2 ("Use by: 01 Dec 2026") or 251131P2 ("Use by: 01 Dec 2026").
- Wash items and surfaces that may have touched the recalled formula using hot soapy water or a dishwasher.
- Watch infants closely for the symptoms listed above. Symptoms of infant botulism can take as long as several weeks to develop, so caregivers should remain vigilant if they used the recalled lots of infant formula.
- Seek immediate medical care if your child shows any signs of illness or you are concerned about exposure.

For Food Distributors (Stores, Food Banks, etc.)

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

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Further Information

For more detailed information on the affected products and ongoing updates regarding this issue, please refer to the official CDC and FDA advisories:

1. **CDC Advisory:** [Infant Botulism Outbreak Linked to Infant Formula, November 2025](#)
2. **FDA Advisory:** [Outbreak Investigation of Infant Botulism: Infant Formula, November 2025](#)

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