

FDA's advisory on all recalled ByHeart Whole Nutrition Infant Formula and Anywhere Pack™ products -- 11/14/25 update



The FDA is advising parents and caregivers **not to buy or feed any ByHeart Whole Nutrition Infant Formula and Anywhere Pack™ products to infants**. For more information about the recall, please visit [ByHeart Broadens Voluntary Recall While Investigation Continues | FDA](#).

There is a suspected case of infant botulism identified in Massachusetts associated with this recall.

DPH is asking local health departments to support recall effectiveness checks in retail establishments and respond to questions from parents in your communities.

Infant botulism is a rare but very serious disease that can damage the nerves, leading to weakness and paralysis. It occurs when *Clostridium botulinum* spores are ingested and grow in an infant's intestinal tract. The bacteria produce toxins that affect the nervous system.

If an infant shows any of these symptoms, parents should seek medical care immediately.

Parents and caregivers with concerns should contact their healthcare provider.

Infants with botulism may show:

- Constipation
- Poor feeding
- Difficulty sucking or swallowing
- Drooping eyelids (ptosis)
- Sluggish pupils
- Low muscle tone
- Weak or altered cry
- Loss of head control
- Generalized weakness
- Breathing difficulty
- Respiratory arrest

Visit [Outbreak Investigation of Infant Botulism: Infant Formula \(November 2025\) | FDA](#) to review further details on the outbreak. ByHeart Whole Nutrition Infant Formula and Anywhere Pack™ products are sold in Massachusetts and nationally in the U.S. and were previously available through multiple retailers including **Shaws, Target, Walmart, Whole Foods, Star Market, and Wegmans.**

Recommended Actions for Local Health Departments

1. Retailer Outreach (as needed)

If your city or town has retailers that may carry infant formula, you may contact them to ensure:

- Recalled ByHeart products have been **removed from shelves** and **not available for purchase**, including returned items.
- Staff are aware of the recall and know not to restock affected product.
- Complete the Recall Effectiveness Check and return the checklist to the Division of Food Protection.

2. Responding to Resident Inquiries

You may advise residents:

- **Do not use** ByHeart formula products.
- If an infant consumed ByHeart formula and has **symptoms**, seek medical care **immediately**.
- If the infant consumed the product but is **not currently symptomatic**, caregivers should monitor closely over the next several weeks.
- Caregivers should **save the container**, record the lot information, and **label it “DO NOT USE.”**
- If no symptoms develop after 30 days, the product may be discarded unless otherwise directed by DPH.

3. Ongoing Monitoring

This is an **active and evolving investigation**. The FDA and CDC continue to identify new information, including additional affected lots and cases.

DPH will share updates as they become available.

You can also view the link in your browser by using the following URL:

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/byheart-broadens-voluntary-recall-while-investigation-continues>