



# FDA RECALL ALERT NOVEMBER 2025

# ByHeart Whole Nutrition Infant Formula

## FDA's Advisory on all Recalled ByHeart Whole Nutrition Infant Formula and Anywhere Pack™ Products

**November 18<sup>th</sup>, 2025**

In response to the Food and Drug Administration (FDA)'s investigation of infant botulism in babies across the United States, the FDA is advising parents and caregivers **not to buy or feed any ByHeart Whole Nutrition Infant Formula and Anywhere Pack™ products to infants**. As of today, **there have been no confirmed cases** of infant botulism in Massachusetts.



### Infant Botulism

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.

#### Infants with botulism may show the following symptoms:

- 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

**If an infant shows any of the above symptoms, parents and/or caregivers should seek medical care immediately. Parents and caregivers with concerns should contact their healthcare provider.**

### Additional Information

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.**

- **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.

### Massachusetts Department of Public Health

For more information on COVID-19 vaccines from MA DPH scan the QR code



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