



## PRESS RELEASE

**FOR IMMEDIATE RELEASE**

**Nov. 19, 2025**

### **Breastfeeding International Calls for Transparency and Accountability in ByHeart Infant Formula Recall**

Breastfeeding International is calling for full transparency and accountability following the rising number of infant botulism cases linked to ByHeart powdered infant formula and the subsequent nationwide recall.

Infant botulism is a rare but life-threatening condition caused by *Clostridium botulinum* bacteria, which produce a neurotoxin that can cause respiratory failure, muscle weakness and prolonged hospitalization. The severity of the recent 2025 outbreak, which has hospitalized 23 infants in 13 states as of this date, is further underscored by a December 2023 Food and Drug Administration (FDA) inspection. The FDA classified ByHeart's facility at the highest tier of concern, known as "Official Action Indicated" (OAI), following that inspection. Inspectors reported multiple critical safety violations, including a leaking roof, mold in a water tank and more than 2,500 dead insects in a food-production area, according to the FDA inspection report as reported by The New York Times. This 2023 inspection was a follow-up to an earlier ByHeart recall in December 2022 due to *Cronobacter sakazakii* control failures. While *C. sakazakii* and *C. botulinum* are different types of bacteria, food safety experts note that these repeated inspection findings demonstrated a pattern of safety concerns within the company that preceded the 2025 botulism outbreak.

"Our thoughts are with the infants, the affected families and the health workers caring for them," the organization said.

Breastfeeding International is urging an independent and transparent investigation into ByHeart's manufacturing processes, environmental monitoring systems and product testing protocols, and is calling for immediate regulatory actions to protect infant health.

#### **Breastfeeding International urges the following actions:**

##### **1. Full disclosure and independent oversight.**

ByHeart must provide FDA investigators unrestricted access to production data, environmental testing results and product tracebacks.

## **2. Protection and support for affected families.**

Families impacted by this outbreak should receive appropriate medical, legal and financial support.

## **3. Suspension of all marketing activities.**

ByHeart should immediately halt promotional and advertising activities and comply fully with the International Code of Marketing of Breastmilk Substitutes. Safety — not sales — must remain the priority.

## **4. Full implementation of the International Code of Marketing.**

Governments must enforce the International Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly resolutions. The Code protects both formula-fed and breastfed infants from harmful commercial practices.

## **5. Strengthened regulation and enforcement.**

This outbreak highlights systemic gaps in surveillance and oversight of powdered infant formula. The FDA must strengthen independent monitoring, recall procedures and public notification systems, protected from commercial interference and lobbying.

“When breastmilk substitutes are used, they must be produced and regulated with unwavering commitment to safety and transparency,” the organization said. “Infants’ health and protection are non-negotiable.”

Breastfeeding International stands in solidarity with families affected by this emergency and calls on ByHeart to act transparently and responsibly.

### **About**

Breastfeeding International is a 501(c)(3) and works to uphold the human rights of women and children – empowering them not only to survive, but to thrive – by protecting, promoting and supporting health, nutrition and breastfeeding.

[Breastfeedinginternational.org](http://Breastfeedinginternational.org)

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