



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

## **Infant Formula Recall Linked to Infant Botulism**

*Potential Case Being Investigated in North Carolina;  
Product is Sold Nationwide*

**FOR IMMEDIATE RELEASE**  
Nov. 10, 2025

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RALEIGH — The North Carolina Department of Health and Human Services and North Carolina Department of Agriculture and Consumer Services are alerting providers, parents and caregivers of an outbreak of infant botulism that prompted a [nationwide recall](#) of ByHeart Inc. Whole Nutrition Infant Formula. As of Nov. 8, there were 13 confirmed cases of infant botulism across 10 states according to the U.S. Food and Drug Administration. There is one suspected case currently under investigation in North Carolina.

Currently, two lots of ByHeart Inc. Whole Nutrition Infant Formula have been voluntarily recalled to date, with investigations ongoing:

- Lot: 206VABP/251261P2 ("Use by 01 Dec 2026")
  - Lot: 206VABP/251131P2 ("Use by 01 Dec 2026")
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Image of recalled product from FDA website:



*ByHeart Inc. Whole Nutrition Infant Formula*

“Our Food and Drug Protection Division is working with counterparts at the Food and Drug Administration and NCDHHS on this recall. Our Food and Drug Protection Division is also working with retailers to make sure they have been notified about the recalled product and are removing it from store shelves,” said **Agriculture Commissioner Steve Troxler**. “However, this product is readily available online and may be in home pantries, so parents need to check to be sure they are not feeding the product to their infants.”

[Botulism](#) is a rare but serious paralytic illness caused by a nerve toxin produced by a bacteria known as *Clostridium botulinum*. All forms of botulism can be fatal and are considered medical emergencies.

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[NCDHHS sent a provider memo](#) to health care providers Monday morning as they should be alert of infants with symptoms consistent with infant botulism.

“Infant botulism is a serious illness and can be life-threatening,” said **Dr. Kelly Kimple, Director of the NCDHHS Division of Public Health**. “NCDHHS is working with our public health and healthcare partners to be sure parents are not using the recalled formula so more babies in North Carolina won’t be exposed.”

If you have purchased an impacted lot of ByHeart Inc. Whole Nutrition Infant Formula, do not use the formula; throw it away or return it to where you bought it. You should also wash items and surfaces that may have touched the recalled formula using hot soapy water or a dishwasher. If possible, you should record the lot number or take a picture of the product prior to disposal or return of the product.

Symptoms of infant botulism can take as long as several weeks to develop, so parents should remain vigilant if they used the recalled lots of formula. Parents or guardians should seek immediate medical care if your infant consumed ByHeart Inc. Whole Nutrition Infant Formula and has any of these symptoms:

- Poor feeding
- Difficulty swallowing
- Decreased facial expression
- Loss of head control
- Respiratory difficulty

ByHeart Inc. Whole Nutrition Infant Formula represents about 1% of infant formula sales across the country and the recall does not create shortage concerns. It is not a SNAP/WIC eligible product, and there are many other options caregivers can use.

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