



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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DEBRA FARRINGTON • Deputy Secretary for Health

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To: Pediatric Healthcare Providers
From: Zack Moore, MD, MPH, State Epidemiologist
Subject: Infant Botulism Linked to Infant Formula
Date: November 10, 2025

This memo was updated November 12, 2025 with updated case and recall information.

On November 8, [CDC](#) and [FDA](#) alerted states to an outbreak of infant botulism linked to ByHeart Whole Nutrition Infant Formula. An initial recall for two lots was issued on November 8, and expanded on November 11 to include all ByHeart Whole Nutrition Infant Formula products. As of November 11, there were 15 cases in 12 states. One suspect case has been identified in North Carolina. Clinicians should be alert for infants presenting with symptoms consistent with infant botulism.

If infant botulism is suspected, call the [Infant Botulism Treatment and Protection Program](#) immediately at 510-231-7600. Consultation is available 24/7. If clinical consultation supports infant botulism, treatment should begin as soon as possible. Your local health department or the state Communicable Disease Branch (919-733-3419) should also be notified.

Parents should be instructed to not use recalled formula and to wash items and surfaces that may have touched the recalled formula using hot soapy water or a dishwasher. If possible, families 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.

Clinical Background

Infant botulism occurs when spores of *Clostridium botulinum* or related species of bacteria are swallowed. The spores temporarily colonize an infant's large intestine and produce botulinum neurotoxin.

Infants with botulism generally present with some or all of the following symptoms:

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LOCATION: 5605 Six Forks Road, Building 3, Raleigh, NC 27609
MAILING ADDRESS: 1931 Mail Service Center, Raleigh, NC 27699-1931
www.ncdhhs.gov • TEL: 919-707-5000 • FAX: 919-870-4829

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- Constipation
- Poor feeding, including difficulty swallowing
- Ptosis, sluggish pupils
- Flattened facial expression
- Loss of head control
- Diminished suck and gag reflexes
- Weak and altered cry
- Respiratory difficulty and possibly respiratory arrest

Recalled Formula

All ByHeart Inc Whole Nutrition Infant Formula products, including cans and single-serve products.

Images of recalled product from [FDA website](#):





