



November 10, 2025

Provider Alert: Cluster of Infant Botulism cases believed to be associated with ByHeart Whole Nutrition Infant Formula. Currently 13 cases, including 2 in California, are being investigated.

Physicians/Providers who suspect a case of infant botulism should:

- Call California's Infant Botulism Treatment and Prevention Program at (510) 231-7600. This is the only source for BabyBIG.
- Notify the local health department immediately at (707) 268-2182 during business hours or (707) 445-7251 after hours/holidays/weekends.
- If possible, collect the infant formula powder for possible testing, and the brand and lot number involved.

Typical signs and symptoms of Infant botulism often begin with:

- Constipation
- Difficulty feeding (sucking and swallowing)
- Poor head control
- A weak and altered cry
- Diminished facial expression
- Other signs of muscle weakness

Treatment:

The antitoxin BabyBIG is the only FDA-approved treatment for infant botulism. BabyBIG has been shown to reduce the length of hospital stays and treatment costs for infants with botulism and remains the standard first-line therapy for infant botulism. California's Infant Botulism Treatment and Prevention Program, which developed BabyBIG, is the only source of infant botulism treatment in the world,

Public Health Investigation

CDPH has tested a can of powdered infant formula that was fed to an infant with infant botulism. Preliminary results suggest the presence of the bacteria that produce botulinum toxin, consistent with the same toxin reported in the confirmed infant cases. CDC, CDPH, and other state health departments are investigating 13 suspected or confirmed infant botulism cases linked to ByHeart powdered infant formula across 10 states. The affected infants had become ill starting in August 2025. Eight of those cases have since been confirmed as toxin type A botulism, with tests pending for the other cases. The investigation into lots of ByHeart powdered infant formula and potential sources of botulism in infants is ongoing.



On November 8, 2025, ByHeart Inc. recalled two lots of Whole Nutrition Infant Formula:

- Lot: 206VABP/251261P2 (“Use by 01 Dec 2026”)
- Lot: 206VABP/251131P2 (“Use by 01 Dec 2026”)

Full Report available here: [California Alerted CDC of Multistate Infant Botulism Outbreak Linked to ByHeart Infant Formula](#)

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