

# DPHHS HAN

## ADVISORY

### Cover Sheet

#### DATE

Nov. 10, 2025

#### SUBJECT

ByHeart Whole Nutrition Infant Formula Recall Due to Risk of Infant Botulism

#### INSTRUCTIONS

**DISTRIBUTE** to your local HAN contacts. This HAN is intended for general sharing of information.

- Time for Forwarding: **As Soon As Possible**
- **Remove this cover sheet before redistributing and replace it with your own**



**For LOCAL/TRIBAL HEALTH DEPARTMENT reference only**  
DPHHS Subject Matter Resource for more information regarding this HAN, contact:

DPHHS PHSD

**Epidemiology Section**  
**1-406-444-0273**

**Environmental Health and Food Safety Section**

**1-406-444-5055**

*For technical issues related to the HAN message contact the Emergency Preparedness Section at 1-406-444-0919*

**REMOVE THIS COVER SHEET BEFORE REDISTRIBUTING AND REPLACE IT WITH YOUR OWN**

DPHHS HAN Website:  
<https://dphhs.mt.gov/publichealth/phep/han>

Please ensure that DPHHS is included on your HAN distribution list.  
[hhshan@mt.gov](mailto:hhshan@mt.gov)

#### Categories of Health Alert Messages:

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; unlikely to require immediate action.

**Information Service:** passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

**Please update your HAN contact information on the Montana Public Health Directory**

# DPHHS HAN

## Information Sheet



### DATE

Nov. 10, 2025

### SUBJECT

ByHeart Whole Nutrition Infant Formula Recall Due to Risk of Infant Botulism

### BACKGROUND

Since August, 13 cases of infant botulism in infants who consumed ByHeart brand powdered infant formula have been reported to CDC from 10 states. States reporting cases include Arizona, California, Illinois, Minnesota, New Jersey, Oregon, Pennsylvania, Rhode Island, Texas, and Washington. The cases range in age from 16 days to several months old. To date, no deaths have been reported. Among cases with confirmatory testing, six have been confirmed, with testing showing the presence of botulinum toxin type A. Testing is pending for the remaining cases. No cases have been identified in Montana to date.

ByHeart is a small producer of powdered infant formula. Their product is distributed throughout the United States, including retail stores in Montana as well as online merchants. This firm has a relatively low market share in the powdered infant formula market compared to other manufacturers. The high number of infant botulism cases reporting use of this brand is highly unusual and represents a significant epidemiological signal.

### INFORMATION

FDA issued communications about a recall of two lots of powdered infant formula. Recall of this product is not expected to create infant formula shortage concerns.

Affected lots are:

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

Retailers and consumers are advised to regularly check the FDA website for up-to-date recall information as the outbreak investigation continues. The link to the recall is: <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025>.

### CLINICAL PRESENTATION

Infant botulism is the most common type of botulism in the United States. Symptoms usually present in children less than twelve months of age and include constipation, loss of appetite, weakness, poor suck, ocular palsies, an altered cry, and a striking loss of head control. Progression of symptoms is more severe in infants under two months of age. Infants become infected by ingestion of *C. botulinum* spores that germinate in the colon, rather than ingestion of preformed toxin. It can take up to 30 days from the date of exposure to develop signs and symptoms.

## RECOMMENDATIONS

Infants should **not** be fed the recalled formula. Parents and caregivers should stop using the affected product immediately and, if a child exhibits symptoms, record the information from the bottom of the package before disposing of it.

### Health Care Providers

- DPHHS recommends that providers maintain heightened suspicion for the possibility of infant botulism in any infant presenting with compatible symptoms who was fed ByHeart powdered infant formula.
- Additionally, providers should ask which formula brand is fed to their infant patients, alert parents/guardians to the ByHeart recall, and ensure recalled formula is not used.
- Physicians who suspect an infant patient has botulism should immediately call the California Department of Public Health (CDPH) Infant Botulism Treatment and Prevention Program at 510-231-7600 for case consultation 24/7.
  - If clinical consultation supports infant botulism, begin treatment as soon as possible. Do not wait for laboratory confirmation.
- Providers should report suspect botulism cases to the [local or tribal health department](#) of the patient's jurisdiction of residence immediately.

### Local and Tribal Health Departments

- Local and tribal health departments should immediately call the Communicable Disease Epidemiology section at 406-444-0273 if they have a suspect botulism case in their jurisdiction.

## RESOURCES

Updates on this outbreak and additional information can be found on CDC's website: [Infant Botulism Outbreak Linked to Infant Formula, November 2025](#)