

STATE OF HAWAI'I KA MOKU 'ĀINA O HAWAI'I

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DEPARTMENT OF HEALTH

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DOH ALERTS PUBLIC ABOUT RECALL OF BYHEART INFANT FORMULA DUE TO POTENTIAL CONTAMINATION

25-134

FOR IMMEDIATE RELEASE

November 10, 2025

HONOLULU – The Hawai'i Department of Health (DOH) Food and Drug Branch (FDB) is alerting residents to a recall issued by ByHeart Inc. for select lots of ByHeart Whole Nutrition Infant Formula product, due to potential contamination of *Clostridium botulinum*.

The recalled product is under investigation by the U.S. Food and Drug Administration (FDA) and the agency has issued a warning to parents and caregivers to stop using certain batches of the formula.

The product was distributed nationwide, including direct-to-consumer sales from the ByHeart website and via Amazon, and was available locally from retailers like Target. FDB is working with the local stores to ensure that the recalled product is no longer available for sale. This recall currently applies to two batches identified as follows, however additional testing of other batches and products from ByHeart Inc. is also being evaluated:

Size	Batch Code	Use By Date	UPC
24 oz	251261P2	01 Dec 2026	5004496800
24 oz	251131P2	01 Dec 2026	5004496800

Infant botulism is a rare but potentially fatal illness that presents a serious threat to the health of infants when *Clostridium botulinum* spores are ingested and colonize in the

intestinal tract. Affected infants can present with some or all of the following signs and symptoms: constipation, poor feeding, ptosis (drooping eyelid), sluggish pupils, low muscle tone, difficulty sucking and swallowing, weak or altered cry, generalized weakness, respiratory weakness, respiratory difficulty and possibly respiratory arrest.

Please contact your healthcare provider immediately if your infant is exhibiting these symptoms after having consumed the recalled product within the past 30 days.

The FDB advises consumers to verify the recalled product by checking the batch code and best if used by date printed on the bottom of the can. Consumers who have purchased the recalled product should immediately discontinue use and dispose of the product or return it for a refund. Any utensils, feeding bottles, and other implements should be thoroughly washed with hot, soapy water. Consumers with questions should contact ByHeart Inc. via email at hello@byheart.com or call 1-833-429-4327 24 hours/day, 7 days/week.

A representative product photograph and photograph of the specific recalled labels are listed below:







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