

**From:** [AgencyServices](#)  
**Subject:** Byheart Issues Voluntary Recall of Five Batches of Its Infant Formula Because of Possible Health Risk  
**Date:** Tuesday, December 27, 2022 9:35:25 AM

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**Company Announcement Date:**

December 11, 2022

**FDA Publish Date:**

December 11, 2022

**Product Type:**

Food & Beverages

**Reason for Announcement:**

Potential for cross-contamination with *Cronobacter sakazakii*

**Company Name:**

ByHeart

**Brand Name:**

ByHeart

**Product Description:**

Whole Nutrition Infant Formula, Milk Based Powder with Iron for 0-12months

None of the distributed ByHeart product has tested positive for any contaminants

No consumer complaints received, to date, that would indicate any illness

Recall is not related to ByHeart's own manufacturing facility in Reading, PA in any way; facility continues to run 24/7; re-stock expected in January

[ByHeartExternal Link Disclaimer](#), a next-generation baby nutrition company, announced today that, out of an abundance of caution, it has chosen to voluntarily recall five batches of ByHeart Whole Nutrition Infant Formula due to the potential for cross-contamination with *Cronobacter sakazakii*. No distributed ByHeart product has tested positive for the bacteria.

The product being recalled is ByHeart Whole Nutrition Infant Formula, Milk Based Powder with Iron for 0-12 Months in 24 oz containers. **The formula under voluntary recall was distributed directly to consumers in the U.S.** and can be identified by the number on the bottom of the can. **Recalled product batches are 22273 C1, 22276 C1, 22277 C1, 22278 C1, and 22280 C1 printed with use by 01 JAN 24 or 01JUL 24.**

*Cronobacter* bacteria can cause severe, life-threatening infections (sepsis) or meningitis (an inflammation of the membranes that protect the brain and spine). Symptoms of sepsis and meningitis may include poor feeding, irritability, temperature changes, jaundice (yellow skin and whites of the eyes), grunting breaths and abnormal movements. *Cronobacter* infection may also cause bowel damage and may spread through the blood to other parts of the body.

It is important to note that this recall is not related to ByHeart's own manufacturing in any way. In addition, the company has not received any consumer complaints that would indicate any illness, to date; illness complaints are an early detection of safety concerns. If a baby has already consumed all of the formula, there is no reason for concern, and no additional action is needed. If parents have any questions, they should consult with their pediatrician.

ByHeart owns its entire manufacturing supply chain with the exception of final canning, which is conducted by a reputable third-party packager. ByHeart is taking this precautionary measure because one test sample collected from the third-party packaging facility tested positive for *Cronobacter sakazakii*. All product packaged that day, and the first production on the next day, was isolated for destruction and not distributed. Out of an abundance of caution, we are now recalling all product produced during the entire production run.

As a company committed to parents, ByHeart holds itself to the highest standards when it comes to safety and applauds the FDA's efforts to oversee the safe manufacturing of infant formula. Parents can remain confident in the safety of ByHeart's products as the company continues to expand its investments in infant formula innovation, clinical studies, and industry-leading quality standards. ByHeart's manufacturing facility in Reading, PA, continues to operate 24/7, and the company is committed to providing customers formula in January.

**What ByHeart Customers Should Do**

Customers who purchased ByHeart product should check the bottom of the can and dispose of product from batches

22273 C1, 22276 C1, 22277 C1, 22278 C1, and 22280 C1. ByHeart is setting up a webpage at <https://byheart.com/noticesExternal Link Disclaimer> with additional information about its measures. Should customers have any other questions or want to find out if the product they have is included in the voluntary recall, please email [notices@byheart.com](mailto:notices@byheart.com) or text ByHeart at 1-909-506-2354. The company will also be reaching out directly to all customers via email who purchased orders from these identified batches.

ByHeart knows that formula is critical to a baby's health and growth and wants to make sure that all customers have what they need to keep their baby fed and healthy, no matter what brand of formula they use. While ByHeart works 24/7 to meet the demand for formula, the fastest way the company can replace the formula customers purchased is to cover the cost of two cans of alternate formula. Additionally, affected customers will receive two cans of their next order of ByHeart Whole Nutrition Formula for free.

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/byheart-issues-voluntary-recall-five-batches-its-infant-formula-because-possible-health-risk>

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\* We believe that none of the product being recalled were processed or offered through the national office

\* We strongly encourage you to notify your agencies within one business day from receipt of this notice.

\* ALL cased and uncased inventories, both at the member level and agency level, need to be checked. This product may have entered member and agency warehouses through salvage, local donations, TEFAP, local purchases, retail pickups, food drives, or other avenues.

\* For additional local details, please contact the Health Department(s) for the area(s) your food bank serves.

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#### **About Feeding America Recall Notices**

The Feeding America national office issues notifications of all national Class I and II recalls--those involving a health hazard situation in which there is reasonable probability that eating the food will cause health problems or death--and other recalls that may affect the safety of food supplied to network members.

The national office strongly encourages all member product solicitors, operations managers, and others involved in food and grocery distribution to regularly consult resources provided by the United States Food and Drug Administration (FDA) at <http://www.fda.gov/opacom/7alerts.html>, and the United States Department of Agriculture (USDA) at [http://www.fsis.usda.gov/Fsis\\_Recalls/index.asp](http://www.fsis.usda.gov/Fsis_Recalls/index.asp). Additionally, members can often receive information on national, state, and local recalls by contacting their local health departments.

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