

FDA Recall – ByHeart Whole Nutrition Infant Formula

Purpose of this communication:

- We are writing to inform you that ByHeart, a next-generation baby nutrition company, announced that, out of an abundance of caution, it has chosen to voluntarily recall two batches of ByHeart Whole Nutrition Infant Formula following notification from the U.S. Food and Drug Administration (FDA) of a broader ongoing investigation into a recent outbreak of infant botulism.
- ByHeart was notified by the FDA on November 7, 2025 of an estimated 83 cases of infant botulism that were reported nationwide since August 2025. Of these, the FDA also noted that 13 infants received ByHeart formula at some point. The FDA has not identified a direct link between any infant formula and these cases and there is no historical precedent of infant formula causing infant botulism. Botulism is extremely uncommon in dairy products or infant formula, and is naturally occurring in environmental sources like soil, select vegetables, and dust. The impacted batch codes include 251261P2, Use by: 01 Dec 2026 and 251131P2, Use by: 01 Dec 2026 with a UPC of 5004496800.

What do I need to do?

- Please review the following recall notice: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/response-broader-fda-investigation-byheart-initiates-voluntary-recall-two-batches-infant-formula>
- Notify impacted patients and facilitate the resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.