

## FDA Issues Warning Letters to Three Infant Formula Manufacturers

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- On August 30, 2023, the U.S. Food and Drug Administration (FDA) issued warning letters to three infant formula manufacturers as part of the Agency's recent push to enhance regulatory oversight in the infant formula industry. The warning letters, which were issued to [ByHeart Inc.](#), [Mead Johnson Nutrition](#), and [Perrigo Wisconsin, LLC](#), allege violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the FDA's Infant Formula regulations.
- At the time of FDA inspections of the facilities, the Agency issued inspectional observations and exercised oversight of each firm as they initiated recalls (in [December 2022](#), [February 2023](#) and [March 2023](#)) to remove product potentially contaminated with *Cronobacter sakazakii* from the marketplace.
- Importantly, FDA does not advise consumers to discard or avoid purchasing any particular infant formula at this time. These warning letters are not associated with any current recalls and therefore, FDA does not anticipate any impact to the availability of infant formula on the market. Consumers should know that the U.S. infant formula supply is healthy with in-stock rates at 85% or higher since the beginning of 2023.
- FDA [states](#) that it is issuing these letters now "as part of its normal regulatory process and to reinforce to these firms the importance of instituting and maintaining appropriate corrective actions when they detect pathogens to ensure compliance with the FDA's laws and regulations." Each company will have 15 working days to respond to the FDA to explain what corrective actions they are taking.

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