

## FDA NEWS RELEASE

# FDA Infant Formula Update: July 6, 2022

### For Immediate Release:

July 06, 2022

Today, the U.S. Food and Drug Administration is providing an update on additional steps it has taken that will lead to more infant formula available in the U.S. under the agency's [recent increased flexibilities](https://www.fda.gov/news-events/press-announcements/fda-encourages-importation-safe-infant-formula-and-other-flexibilities-further-increase-availability) (<https://www.fda.gov/news-events/press-announcements/fda-encourages-importation-safe-infant-formula-and-other-flexibilities-further-increase-availability>).

**Company (Product Origin):** Vitaflo USA LLC (The Netherlands)

**Product(s):** PKU Start

**Type of Formula:** Specialty/metabolic formula for infants with phenylketonuria (PKU), a rare genetic disorder in which the amino acid phenylalanine builds up in the body.

**Estimated Quantity:** 3,192 cans (about 2,815 pounds or about 39,844 full-size, 8-ounce bottles)

**Availability:** Product will be available within two weeks through direct purchase from Vitaflo and medical distribution channels, with a second round of product expected to be available in September.

**More Information and Where to Find the Products:** PKU Start must be used under medical supervision and is available directly from Vitaflo with a medical prescription. It will be distributed through medical distribution channels such as pharmacies, durable medical equipment providers, Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and home care providers. These designated providers can place an order on behalf of patients by calling Vitaflo at 888-848-2356.

The FDA is exercising enforcement discretion for the importation of the infant formula products listed above following the review of information provided pertaining to nutritional adequacy and safety, including microbiological testing, labeling and additional information about facility production and inspection history.

The agency is leveraging a number of flexibilities to bolster the supply of products that serve as the sole source of nutrition for many infants while ensuring the infant formula can be used safely and provides adequate nutrition. The FDA remains in further discussions with manufacturers and suppliers regarding additional supply to ensure there's adequate infant formula available wherever and whenever parents and caregivers need it.

The FDA issued [guidance \(/news-events/press-announcements/fda-encourages-importation-safe-infant-formula-and-other-flexibilities-further-increase-availability\)](#) on May 16 that outlined a process by which the agency would not object to the importation of certain infant formula products intended for a foreign market or distribution in the U.S. of products manufactured here for export to foreign countries. This guidance also may provide flexibilities to those who manufacture infant formula products domestically and may be able to further increase the quantity of domestically-produced product for the U.S. market. The agency has posted a [webpage \(/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies\)](#) that will be updated with information about additional products headed to the U.S.

### **Ongoing FDA Steps to Increase Availability of Safe, Nutritious Infant Formula**

The agency's around-the-clock work as part of the all-of-government efforts has already begun to improve supply and availability. The agency expects that the [measures and steps it is taking \(/news-events/press-announcements/fda-takes-important-steps-improve-supply-infant-and-specialty-formula-products\)](#), and the resumption of production at the Abbott Nutrition's Sturgis, Mich., facility, will mean more and more supply is on the way or on store shelves moving forward.

The FDA continues to [advise against making infant formulas at home or diluting formula \(/food/alerts-advisories-safety-information/fda-advises-parents-and-caregivers-not-make-or-feed-homemade-infant-formula-infants\)](#). Parents and caregivers are encouraged to work with their child's health care provider for recommendations on changing feeding practices, if needed. The U.S. Department of Health and Human Services also has additional information available at [HHS.gov/formula \(https://www.hhs.gov/formula/index.html\)](#), including information to help families find infant formula.

The agency also monitors online marketplaces for fraudulent products and works with major online retailers to remove violative and harmful products offered for sale on their sites. Additionally, since many of these fraudulent products originate overseas, the agency targets and examines these products at ports of entry. The FDA also monitors and follows up on various external signals such as consumer complaints about potential counterfeit and fraudulent products.

The FDA will continue to dedicate all available resources to help ensure that safe and nutritious infant formula products remain available for use in the U.S. and will keep the public informed of progress updates.

## Related Information

- [Infant Formula Information and Ongoing FDA Efforts to Increase Supply](https://www.fda.gov/news-events/public-health-focus/infant-formula-information-and-ongoing-fda-efforts-increase-supply)  
(<https://www.fda.gov/news-events/public-health-focus/infant-formula-information-and-ongoing-fda-efforts-increase-supply>)
- [Enforcement Discretion to Manufacturers to Increase Infant Formula Supplies](https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies)  
(<https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies>)
- [HHS.gov/formula](https://www.hhs.gov/formula/index.html) (<https://www.hhs.gov/formula/index.html>)
- [HHS.gov/news](https://www.hhs.gov/about/news/index.html) (<https://www.hhs.gov/about/news/index.html>)
- [FDA Investigation of Cronobacter Infections: Powdered Infant Formula \(February 2022\)](https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022)  
(<https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022>)
- [Powdered Infant Formula Recall: What to Know](https://www.fda.gov/consumers/powdered-infant-formula-recall-what-know)  
(<https://www.fda.gov/consumers/powdered-infant-formula-recall-what-know>)
- [CDC Information on Cronobacter Infection and Infants](https://www.cdc.gov/cronobacter/infection-and-infants.html)  
(<https://www.cdc.gov/cronobacter/infection-and-infants.html>)

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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