

FDA launches Operation Stork Speed to expand options for safe, reliable, nutritious infant formula

September 1, 2025

Food and Drug Administration

Article type: [FDA Update](#)

Topics: [Fetus/Newborn Infant](#), [Nutrition](#)

The U.S. Food and Drug Administration (FDA) has initiated Operation Stork Speed, a comprehensive program aimed at improving the safety and nutritional quality of infant formula.

While the FDA supports breastfeeding as the best source of nutrition for infants, many families in the United States rely on infant formula for some or all of their babies' nutritional needs.

Although 84% of U.S. infants have ever breastfed or received breastmilk, only 27% are exclusively breastfed through 6 months of age as recommended by the AAP, according to a June 2025 [report](#) from the Centers for Disease Control and Prevention.

Operation Stork Speed encompasses the following key initiatives:

- A comprehensive review of infant formula nutrient requirements.
- Increased testing for heavy metals and other contaminants in infant formula and other foods consumed by young children.
- Extension of the personal importation policy, which allows individual consumers (such as parents or caregivers) to purchase and import infant formula from other countries into the United States for personal use.
- Collaboration with industry to improve transparency and labeling.
- Regular communication with consumers and key stakeholders.
- Partnership with the National Institutes of Health (NIH) to address scientific research gaps.

The FDA already has made progress on these commitments. On May 13, the FDA requested public input on the revision of nutrient requirements based on the latest scientific data (<https://bit.ly/4Lhrlt>). The comment period is open until Sept. 11.

Additionally, the agency is working with NIH to establish a [Nutrition Regulatory Science Program](#) (NRSP) to develop a nutrition and food-related research agenda to inform evidence-based policy solutions. In June, the FDA hosted an expert panel on infant formula to gather perspectives on knowledge gaps and challenges, and the latest scientific developments in the field.

The FDA's regulatory oversight of infant formula includes ensuring safety and nutritional adequacy. While the FDA does not have the regulatory authority to "approve" infant formulas, all formulas marketed in the United States must meet specific federal nutrient requirements. Prior to marketing a new infant formula, manufacturers must submit notification packages that include details on nutrients, ingredients, manufacturing processes, labeling and packaging for review by the FDA's Infant Formula Premarket Review Staff.

Under section 412(i) of the Federal Food, Drug, and Cosmetic Act and Title 21 of the Code of Federal Regulations Part 107.100, "an infant formula must meet specific requirements for the levels of protein, fat, essential fatty acids, 15 vitamins, and 12 minerals."

If an infant formula does not contain these nutrients at or above the minimum level or within the specified range, it is considered an adulterated product, and the FDA has authority to take action to remove the product from the U.S. market.

An adulterated infant formula could, for example, contain harmful substances, lack essential nutrients or be produced under unsafe conditions, which could cause serious health problems in babies, including nutritional deficiencies that may affect growth, bacterial infections, toxic exposure and developmental delays.

If parents learn they have been using an adulterated formula, they should stop using it immediately and contact their pediatrician, especially if their baby shows signs of illness.

In addition to premarket review, the FDA implements several safety initiatives related to infant formula. For example, the agency inspects infant formula facilities annually, collects and analyzes samples of infant formula, and is implementing a strategy to prevent the presence of *Cronobacter sakazakii* in powdered infant formula (<https://bit.ly/4IM58W4>). In addition, the FDA has taken action to improve the resiliency of the U.S. infant formula supply (<https://bit.ly/44Q6ljX>).

With Operation Stork Speed, the FDA reaffirms its dedication to putting science at the forefront to ensure infant formula continues to support children's healthy development.

The FDA's Office of Critical Foods and Infant Formula Premarket Review Staff and Office of Pediatric Therapeutics contributed to this article.

Editor's note: *FDA Update* is provided by the U.S. Food and Drug Administration. AAP News has published this column since 2008 to keep pediatricians up to date on prescription drug indications and other relevant topics.