

# Questions & Answers for Consumers Concerning Infant Formula

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### 1. **What is an Infant Formula?**

The Federal Food, Drug, and Cosmetic Act (FFDCA) defines infant formula as "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk" (FFDCA 201(z)). FDA regulations define infants as persons not more than 12 months old (Title 21, Code of Federal Regulations 21 CFR 105.3(e)). Source: Excerpted from **Guidance for Industry: Frequently Asked Questions about FDA's Regulation of Infant Formula (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/InfantFormula/ucm056524.htm)** March 1, 2006.

### 2. **How does FDA regulate Infant Formulas?**

Because infant formula is a food, the laws and regulations governing foods apply to infant formula. Additional statutory and regulatory requirements apply to infant formula, which is often used as the sole source of nutrition by a vulnerable population during a critical period of growth and development. These additional requirements are found in section 412 of the FFDCA and FDA's implementing regulations in 21 CFR 106 and 107. To view the FFDCA and regulations in 21 CFR, see **FDA Federal Register Documents, Code of Federal Regulations & Food, Drug, and Cosmetic Act (http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm)**. Source: Excerpted from **Guidance for Industry: Frequently Asked Questions about FDA's Regulation of Infant Formula (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/InfantFormula/ucm056524.htm)** March 1, 2006.

### 3. **Does FDA have nutrient specifications for infant formulas?**

Yes, FDA has requirements for nutrients in infant formulas, which are located in section 412(i) of the FFDCA and 21 CFR 107.100. These nutrient specifications include minimum amounts for 29 nutrients and maximum amounts for 9 of those nutrients. If an infant formula does not contain these nutrients at or above the minimum level or within the specified range, it is an adulterated product unless the formula is "exempt" from certain nutrient requirements. An "**exempt infant formula (Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/ucm106456.htm)**" is "any infant formula which is represented and labeled for use by an infant who has an inborn error of metabolism or low birth weight, or who otherwise has an unusual medical or dietary problem" (FFDCA 412(h)(1)). Source: Excerpted from **Guidance for Industry: Frequently Asked Questions about FDA's Regulation of Infant Formula (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/InfantFormula/ucm056524.htm)** March 1, 2006.

### 4. **Does FDA approve infant formulas before they are marketed?**

No, FDA does not approve infant formulas before they can be marketed. However, all formulas marketed in the United States must meet federal nutrient

requirements and infant formula manufacturers must notify the FDA prior to marketing a new formula. If an infant formula manufacturer does not provide the elements and assurances required in the notification for a new or reformulated infant formula, the formula is defined as adulterated under Section 412(a)(1) of the FFDCFA and FDA has the authority to take compliance action if the new infant formula is marketed. Source: Excerpted from **Guidance for Industry: Frequently Asked Questions about FDA's Regulation of Infant Formula** (<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/InfantFormula/ucm056524.htm>) March 1, 2006.

**5. How do parents know what formula to feed to their infant?**

A wide selection of different types of infant formulas is available on the market. Parents should ask their infant's health care provider if they have questions about selecting a formula for their infant. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

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**6. Do infants fed infant formulas need to take additional vitamins and minerals?**

Infants fed infant formulas do not need additional nutrients unless a low-iron formula is fed. If infants are fed a low-iron formula, a health care professional may recommend a supplemental source of iron, particularly after 4 months of age. FDA's nutrient specifications for infant formulas are set at levels to meet the nutritional needs of infants. In addition, manufacturers set nutrient levels for their label claims that are generally above the FDA minimum specifications and they add nutrients at levels that will ensure that their formulas meet their label claims over the entire shelf-life of the product. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

**7. Do "house brand" or generic infant formulas differ nutritionally from name brand formulas?**

All infant formulas marketed in the United States must meet the nutrient specifications listed in FDA regulations. Infant formula manufacturers may have their own proprietary formulations but they must contain at least the minimum levels of all nutrients specified in FDA regulations without going over the maximum levels, when maximum levels are specified. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

**8. Some ingredient statements on infant formula labels include ingredients in addition to nutrients and familiar components such as milk. Why are those ingredients added?**

Ready-to-feed and concentrated liquid formulas often contain ingredients such as lecithin, carrageenan, and mono- and diglycerides added to ensure that the formula doesn't separate during shelf-life. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

**9. What does the "use by" date mean on infant formula product labels?**

The "use by" date on infant formulas is a date, selected by the manufacturer based on tests and other information, to inform retailers and consumers about the quality of the infant formula. Until that declared date, the infant formula will contain no less than the amount of each nutrient declared on the product label and will otherwise be of acceptable quality. The "use by" date is required by

FDA regulations on each container of infant formula. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

**10. What are counterfeit infant formulas? How can I avoid buying such products?**

Counterfeit infant formulas are infant formula products that have been diverted from normal distribution channels and relabeled. Diverted products may be relabeled with counterfeit labels to misrepresent the quality or identity of a formula. For example, if an infant formula is past the "use by" date, a counterfeit label may bear a false "use by" date to obscure the fact that the product may no longer contain the amounts of nutrients listed on the label and may otherwise not be of acceptable quality. As a second example, an infant formula may be relabeled to disguise the true content of the product. Infants who are intolerant to certain ingredients and are fed such a counterfeit formula could experience serious adverse health consequences. To protect infants, parents or other caregivers should always look for any changes in formula color, smell, or taste. Parents should make sure the lot numbers and "use by" dates on the containers and boxes are the same (if buying by the case), check containers for damage, and call the manufacturer's toll-free number with any concerns or questions. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

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**11. I have seen bottled water marked for use in preparing infant formula. What does this mean?**

The manufacturers of infant formula provide directions for mixing their products with water and usually do not specify the source of water other than to indicate that the water should be safe to drink. In most situations, it is safe to mix formula using ordinary cold tap water that is brought to a boil and boiled for one minute or as directed on the label of the infant formula. Some water companies wish to make available bottled waters which are marketed for infants and for use in mixing with infant formula. When manufacturers label their water as intended for infants, the water must meet the same standards established for tap water by the Environmental Protection Agency. The label must also indicate that the bottled water is not sterile. As with tap water, consumers should boil bottled water one minute before mixing with infant formula. Water that is sterilized by the manufacturer and intended for use with infants must meet certain strict FDA standards. Source: Excerpted from **<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/InfantFormula/ucm056524.htm>** March 1, 2006.

**12. Are there approved recipes for homemade infant formulas?**

FDA regulates commercially available infant formulas, which are marketed in liquid and powder forms, but does not regulate recipes for homemade formulas. Great care must be given to the decision to make infant formulas at home, and safety should be of prime concern. The potential problems associated with errors in selecting and combining the ingredients for the formula are very serious and range from severe nutritional imbalances to unsafe products that can harm infants. Because of these potentially very serious health concerns, FDA does not recommend that consumers make infant formulas at home. Source: Excerpted

from **Guidance for Industry: Frequently Asked Questions about FDA's Regulation of Infant Formula (<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/InfantFormula/ucm056524.htm>)** March 1, 2006.

**13. I see formulas on the market that contain ingredients called DHA and ARA. What are these substances?**

DHA is docosahexaenoic acid and ARA is arachidonic acid. Both are long-chain polyunsaturated fatty acids. The body can make DHA and ARA from certain other dietary fatty acids, which are found in plant oils and other sources; however, DHA and ARA are also consumed directly in the diet. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

**14. What foods contain the fatty acids DHA (docosahexaenoic acid) and ARA (arachidonic acid)?**

DHA is contained in varying amounts in fish oils, with oils from cold-water fish containing higher amounts. DHA and ARA are also found in some algae and fungi, eggs, and in human breast milk. Some manufacturers make dietary supplements containing DHA and ARA. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

**15. Why is there interest in adding DHA and ARA to infant formulas?**

While infants can make these fatty acids from other ("essential") fatty acids in their diet, including the fatty acids in infant formulas, some studies suggest that some infants, such as premature infants, may benefit from direct consumption. Other studies suggest no benefit. It is known that long-chain polyunsaturated fatty acids (DHA in particular) accumulate in brain and eye of the fetus, especially during the last trimester of pregnancy. These fatty acids are also found in the fat of human breast milk. Blood levels of DHA and ARA are typically higher in breast-fed infants than in infants fed formulas not containing these fatty acids. For these reasons, some infant formula manufacturers and consumers are interested in providing DHA and ARA directly to infants. These manufacturers and consumers argue that adding oils containing these fatty acids to the fats and oils already in infant formula will provide an infant with both pre-formed DHA and ARA and the essential fatty acids an infant needs to make its own DHA and ARA. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

**16. What is the evidence that addition of DHA and ARA to infant formulas is beneficial?**

The scientific evidence is mixed. Some studies in infants suggest that including these fatty acids in infant formulas may have positive effects on visual function and neural development over the short term. Other studies in infants do not confirm these benefits. There are no currently available published reports from clinical studies that address whether any long-term beneficial effects exist. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

**17. I understand that oils containing DHA and ARA have been added to infant formulas for several years in other countries. Isn't there information from those countries on any long-term benefits or adverse consequences of**

**formulas containing these fatty acids?**

Systematic monitoring efforts are not in place to collect and analyze information on effects of infant formulas containing DHA and ARA in countries where these formulas are in use. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

**18. Why has FDA asked manufacturers to do postmarket surveillance of infants consuming formulas containing ARA or DHA?**

These are new ingredients that were not used in infant formulas in this country before early 2002, and infant formulas containing ARASCO (ARA Single Cell Oil) and DHASCO (DHA Single Cell Oil) have been marketed in other countries for only a few years. FDA views any evaluation of the safety of use of new food ingredients such as DHASCO and ARASCO as a time-dependent judgment that is based on general scientific knowledge as well as specific data and information about the ingredient. Therefore, scientific data that become available after specific products containing a new ingredient enter the market must be considered as a part of the totality of information about the ingredient. Pre-market clinical studies evaluating the effects of infant formulas containing DHASCO and ARASCO on physical growth and some aspects of development are short-term studies, while some studies suggest that feeding of infant formulas with oils containing DHA and ARA to infants may have long-term effects on growth and development. For all these reasons, manufacturers have been asked to closely monitor these new infant formulas in the marketplace. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

**19. How do I report a problem or illness caused by an infant formula?**

If a consumer has a general complaint or concern about a food product including an infant formula, FDA is the appropriate agency to contact. These problems, complaints, or injuries can be reported in writing or by telephone, or by the Internet at **[Report a Problem \(http://www.fda.gov/Safety/ReportaProblem/default.htm\)](http://www.fda.gov/Safety/ReportaProblem/default.htm)**.

If you think your infant has suffered a serious harmful effect or illness from an infant formula, your health care provider can report this by calling FDA's MedWatch hotline at 1-800-FDA-1088 or by using **[Reporting by Health Professionals. \(http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085568.htm\)](http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085568.htm)** The **[MedWatch program \(http://www.fda.gov/Safety/MedWatch/default.htm\)](http://www.fda.gov/Safety/MedWatch/default.htm)** allows health care providers to report problems possibly caused by FDA-regulated products such as drugs, medical devices, medical foods, dietary supplements, and infant formulas. The identity of the patient is kept confidential. In addition, health care providers should report infectious diseases in infants associated with use of infant formula to CDC's Division of Healthcare Quality Promotion (1-800-893-0485).

Consumers may also report an illness, injury or other problem they believe to be related to the use of an infant formula by calling FDA at 1-800-FDA-1088 or using **[Reporting by Consumers. \(http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm\)](http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm)** FDA would like to know when a product may have caused a problem even if you are unsure the product caused the problem

or even if you and the baby do not visit a doctor or clinic.

Infant formula manufacturers provide toll-free telephone numbers on the labels of their products and should be notified about problems, complaints, or injuries caused by their products. Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.

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