Infant Formula Guidance Documents & Regulatory Information

Guidance documents contain nonbinding recommendations.

Information for consumers about FDA's regulation of infant formula, including recommendations for the safe use of formula, see FDA 101: Infant Formula (/ForConsumers/ConsumerUpdates/ucm048694.htm).

For additional information on infant formula, see Consumer Research on Infant Formula and Infant Feeding (/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm080399.htm).

Laws, Regulations, Rules, and Guidance

- **Guidance for Industry: Demonstration of the Quality Factor Requirements Under 21 CFR 106.96(i) for "Eligible" Infant Formulas**
  (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm400036.htm)
  June 2014

- **Final Rule: Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula**
  ○ **FINAL RULE CORRECTIONS: Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula**

- **Draft Guidance for Industry: Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports**
  (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm384451.htm)
February 2014

- **Final Rule: Indirect Food Additives - Adhesives and Components of Coatings**

- **Proposed Rule: The Addition of Minimum and Maximum Levels of Selenium to Infant Formula and Related Labeling Requirements**
  (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm) April 2013

- **Guidance for Industry: Frequently Asked Questions about FDA's Regulation of Infant Formula**
  (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm056524.htm) March 1, 2006

- **FDA Regulations And Critical Information on the Manufacture And Distribution of Infant Formula**

- **Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula: Proposed Rule**

- **Federal Food Drug and Cosmetic Act, Section 412 - Requirements for Infant Formula**
  (/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/FDCACTChapterIVFood/default.htm)

- **61 FR 36154 - 1996 Proposed Rule for Infant Formula: Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors**

- **Current Manufacturing Regulations and Guidelines**
  - 21 CFR 106 (http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=6f92b77abfe77b7451ec064f075d70b8&rgn=div6&view=text&node=21:2.0.1.1.6.3&idno=21) Infant Formula Quality Control Procedures
  - 21 CFR 106.100 (http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=84c940c7f3ab2d02c5d35b679901872e&rgn=div8&view=text&node=21:2.0.1.1.6.3.1.1&idno=21) Records and Reports Regulations
Infant Formula Labeling Requirements

Exempt Infant Formulas

Nutrient Requirements for Infant Formulas

Infant Formula Recall Requirements

Guidelines Concerning Notification and Testing of Infant Formulas

Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers

Exempt Infant Formulas Marketed in the United States by Manufacturer and Category

Infant Formula Products for Export Only

Federal Food, Drug, and Cosmetic Act, Section 801(e)(1)

Clinical Studies of Infant Formulas

• 21 CFR 56 (http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=7e346b318956291ca82aa9bab17c6776&tpl=/ecfrbrowse/Title21/21cfr56_main_02.tpl) Institutional Review Boards

• Clinical Testing of Infant Formulas With Respect to Nutritional Suitability for Term Infants (http://Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/ucm170649.htm) June 1988