

by telephone, to the Director of the appropriate Food and Drug Administration district office specified in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.) the FDA emergency number, 301-443-1240, shall be used. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate Food and Drug Administration district office specified in part 5, subpart M of this chapter.

[47 FR 17025, Apr. 20, 1982, as amended at 54 FR 24891, June 12, 1989; 61 FR 14479, Apr. 2, 1996; 66 FR 17358, Mar. 30, 2001; 66 FR 56035, Nov. 6, 2001; 69 FR 17291, Apr. 2, 2004]

PART 107—INFANT FORMULA

Subpart A—General Provisions

Sec.
107.3 Definitions.

Subpart B—Labeling

107.10 Nutrient information.
107.20 Directions for use.
107.30 Exemptions.

Subpart C—Exempt Infant Formulas

107.50 Terms and conditions.

Subpart D—Nutrient Requirements

107.100 Nutrient specifications.

Subpart E—Infant Formula Recalls

107.200 Food and Drug Administration-required recall.
107.210 Firm-initiated product removals.
107.220 Scope and effect of infant formula recalls.
107.230 Elements of an infant formula recall.
107.240 Notification requirements.
107.250 Termination of an infant formula recall.
107.260 Revision of an infant formula recall.
107.270 Compliance with this subpart.
107.280 Records retention.

AUTHORITY: 21 U.S.C. 321, 343, 350a, 371.

SOURCE: 50 FR 1840, Jan. 14, 1985, unless otherwise noted.

Subpart A—General Provisions

§ 107.3 Definitions.

The following definitions shall apply, in addition to the definitions contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act):

Exempt formula. An exempt infant formula is an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems.

Manufacturer. A manufacturer is a person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula or packages the infant formula in containers for distribution.

References. References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[50 FR 48186, Nov. 22, 1985]

Subpart B—Labeling

§ 107.10 Nutrient information.

(a) The labeling of infant formulas, as defined in section 201(aa) of the Federal Food, Drug, and Cosmetic Act, shall bear in the order given, in the units specified, and in tabular format, the following information regarding the product as prepared in accordance with label directions for infant consumption:

(1) A statement of the number of fluid ounces supplying 100 kilocalories (in case of food label statements, a kilocalorie is represented by the word “Calorie”); and

(2) A statement of the amount of each of the following nutrients supplied by 100 kilocalories:

Nutrients	Unit of measurement
Protein	Grams.
Fat	Do.
Carbohydrate	Do.
Water	Do.
Linoleic acid	Milligrams.
Vitamins:	
Vitamin A	International units.
Vitamin D	Do.
Vitamin E	Do.
Vitamin K	Micrograms.
Thiamine (Vitamin B ₁)	Do.
Riboflavin (Vitamin B ₂)	Do.

Nutrients	Unit of measurement
Vitamin B ₆	Do.
Vitamin B ₁₂	Do.
Niacin	Do.
Folic acid (Folacin)	Do.
Pantothenic acid	Do.
Biotin	Do.
Vitamin C (Ascorbic acid)	Milligrams.
Choline	Do.
Inositol	Do.
Minerals:	
Calcium	Milligrams.
Phosphorus	Do.
Magnesium	Do.
Iron	Do.
Zinc	Do.
Manganese	Micrograms.
Copper	Do.
Iodine	Do.
Sodium	Milligrams.
Potassium	Do.
Chloride	Do.

(b) In addition the following apply:

(1) Vitamin A content may also be declared on the label in units of microgram retinol equivalents, vitamin D content in units of micrograms cholecalciferol, vitamin E content in units of milligram alpha-tocopherol equivalents, and sodium, potassium, and chloride content in units of millimoles, micromoles, or milli-equivalents. When these declarations are made they shall appear in parentheses immediately following the declarations in International Units for vitamins A, D, and E, and immediately following the declarations in milligrams for sodium, potassium, and chloride.

(2) Biotin, choline, and inositol content shall be declared except when they are not added to milk-based infant formulas.

(3) Each of the listed nutrients, and the caloric density, may also be declared on the label on other bases, such as per 100 milliliters or per liter, as prepared for infant consumption.

(4) One of the following statements shall appear on the principal display panel, as appropriate:

(i) The statement "Infant Formula With Iron", or a similar statement, if the product contains 1 milligram or more of iron in a quantity of product that supplies 100 kilocalories when prepared in accordance with label directions for infant consumption.

(ii) The statement "Additional Iron May Be Necessary", or a similar statement, if the product contains less than

1 milligram of iron in a quantity of product that supplies 100 kilocalories when prepared in accordance with label directions for infant consumption.

(5) Any additional vitamin may be declared at the bottom of the vitamin list and any additional minerals may be declared between iodine and sodium, provided that any additionally declared nutrient (i) has been identified as essential by the National Academy of Sciences through its development of a recommended dietary allowance or an estimated safe and adequate daily dietary intake range, or has been identified as essential by the Food and Drug Administration through a FEDERAL REGISTER publication or establishment of a U.S. Recommended Daily Allowance, and (ii) is provided at a level considered in these publications as having biological significance, when these levels are known.

[50 FR 1840, Jan. 14, 1985, as amended at 67 FR 9585, Mar. 4, 2002]

§ 107.20 Directions for use.

In addition to the applicable labeling requirements in parts 101 and 105 of this chapter, the product label shall bear:

(a) Under the heading "Directions For Preparation and Use", directions for:

(1) Storage of infant formula before and after the container has been opened, including a statement indicating that prolonged storage at excessive temperatures should be avoided;

(2) Agitating liquid infant formula before opening the container, such as "Shake Well Before Opening";

(3) "Sterilization" of water, bottle, and nipples when necessary for preparing infant formula for use;

(4) Dilution of infant formula, when appropriate. Directions for powdered infant formula shall contain the weight and volume of powdered formula to be reconstituted.

(b) In close proximity to the "Directions for Preparation and Use" a pictogram depicting the major steps for preparation of that infant formula, such as (for a concentrated formula):