for the exemption of an infant formula from the requirements of section 412(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a), (b), and (c)). Failure to comply with any regulations in subpart C of this part will result in withdrawal of the exemption given under section 412(h)(1) of the Federal Food, Drug, and Cosmetic Act.

(c) Subpart D of this part contains the nutrient requirements for infant formula under section 412(i) of the Federal Food, Drug, and Cosmetic Act. Failure to comply with any regulation in subpart D of this part will render an infant formula adulterated under section 412(a)(1) of the Federal Food, Drug, and Cosmetic Act.

(d) An exempt infant formula is subject to the provisions of §107.50 and other applicable Food and Drug Administration food regulations.

[79 FR 8074, Feb. 10, 2014]

§ 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 person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula or packages or labels the product in a container for distribution. The term ''manufacturer'' does not include a person who prepares, reconstitutes, or mixes infant formula exclusively for an infant under his/her direct care or the direct care of the institution employing such person.

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, as amended at 79 FR 8074, Feb. 10, 2014]

Subpart B—Labeling

§ 107.10 Nutrient information.

(a) The labeling of infant formulas, as defined in section 201(z) 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, supplied by 100 kilocalories, of each of the following nutrients and of any other nutrient added by the manufacturer:

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.
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.
Selenium	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 milliequivalents. 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 Food and Nutrition Board of the Institute of Medicine through its development of a Dietary Reference Intake, or has been identified as essential by the Food and Drug Administration through a FEDERAL REGISTER publication; 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; 79 FR 8074, Feb. 10, 2014; 80 FR 35840, June 23, 2015]

§ 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):