

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 <sub>1</sub> ) .....	Do.
Riboflavin (Vitamin B <sub>2</sub> ) .....	Do.