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3829, 703–790–0295, and may be ordered online at *http://www.3-a.org/*:

(1) 3–A Sanitary Standards, No. 609–03: A Method of Producing Culinary Steam, adopted November 21, 2004, into §106.20(h).

(2) [Reserved]

(c) American Society for Nutrition, 9650 Rockville Pike, Bethesda, MD 20814–3998, 301–634–7279, *http://www.nutrition.org*:

(1) *Physical growth: National Center for Health Statistics percentiles,* Hamill, P.V.V., T.A. Drizd, C.L. Johnson, R.B. Reed, A.F. Roche, and W.M. Moore, *American Journal of Clinical Nutrition,* vol. 32, pp. 607–614, dated March 1979, into §106.96(i)(1)(ii)(c).

(2) [Reserved]

(d) AOAC International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2417, 301–924–7078:

(1) Official Methods of Analysis of AOAC International, 16th ed., dated 1995, into §106.96(i)(2)(ii):

(i) Section 45.3.04, AOAC Official Method 960.48 Protein Efficiency Ratio Rat Bioassay, and

(ii) Section 45.3.05, AOAC Official Method 982.30 Protein Efficiency Ratio Calculation Method.

(2) Official Methods of Analysis of AOAC International, 18th ed., dated 2005, into §106.96(f):

(i) Section 45.3.04, AOAC Official Method 960.48 Protein Efficiency Ratio Rat Bioassay, and

(ii) Section 45.3.05, AOAC Official Method 982.30 Protein Efficiency Ratio Calculation Method.

(e) Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30333, 1–800–232–4636, *http://www.cdc.gov/growthcharts/who_charts.htm.*

(1) *Birth to 24 months:* Boys Head circumference-for-age and Weight-for-length percentiles, dated November 1, 2009, into §106.96(b)(4).

(2) *Birth to 24 months:* Boys Length-for-age and Weight-for-age percentiles, dated November 1, 2009, into §106.96(b)(4).

(3) *Birth to 24 months:* Girls Head circumference-for-age and Weight-for-length percentiles, dated November 1, 2009, into §106.96(b)(4).

(4) *Birth to 24 months:* Girls Length-for-age and Weight-for-age percentiles, dated November 1, 2009, into §106.96(b)(4).

PART 107—INFANT FORMULA

Subpart A—General Provisions

Sec.

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

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

EDITORIAL NOTE: Nomenclature changes to part 107 appear at 81 FR 49895, July 29, 2016.

Subpart A—General Provisions

§107.1 Status and applicability of the regulations in part 107.

(a) The criteria in subpart B of this part describe the labeling requirements applicable to infant formula under section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 343). Failure to comply with any regulation in subpart B of this part will render an infant formula misbranded under section 403 of the Federal Food, Drug, and Cosmetic Act.

(b) The criteria in subpart C of this part describe the terms and conditions

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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

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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;

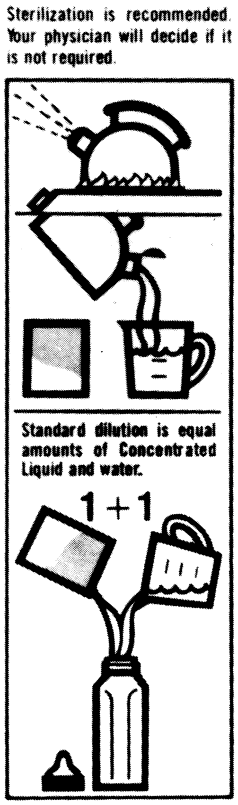
(2) Agitating liquid infant formula before opening the container, such as ''Shake Well Before Opening'';

(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.

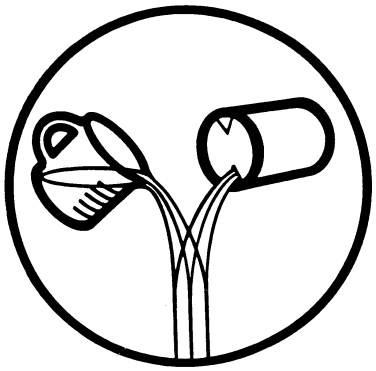
(b) In close proximity to the ''Directions for Preparation and Use'' a pictogram depicting the major steps for preparation of that infant formula, such as (for a concentrated formula):

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(c) A ''Use by _____'' date, the blank to be filled in with the month and year selected by the manufacturer, packer, or distributor of the infant formula on the basis of tests or other information showing that the infant formula, until that date, under the conditions of handling, storage, preparation, and use prescribed by label directions, will: (1) when consumed, contain not less than the quantity of each nutrient, as set forth on its label; and (2) otherwise be of an acceptable quality (e.g., pass through an ordinary bottle nipple).

(d) The statement ''Add Water'' or ''Do Not Add Water'', as appropriate, to appear on the principal display panel of concentrated or ready-to-feed infant formulas. In close proximity to the statement ''Add Water'', a symbol such as



if the addition of water is necessary. The symbol shall be placed on a white background encircled by a dark border.

(e) A warning statement beneath or in close proximity to the ''Directions For Preparation and Use'' that cautions against improper preparation or use of an infant formula, such as ''THE HEALTH OF YOUR INFANT DEPENDS ON CAREFULLY FOLLOWING THE DIRECTIONS FOR PREPARATION AND USE''.

(f) A statement indicating that parents should consult their physicians about the use of infant formulas, such as ''USE AS DIRECTED BY A PHYSICIAN''.

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

§ 107.30 Exemptions.

When containers of ready-to-feed infant formula, to be sold at the retail level, are contained within a multiunit package, the labels of the individual containers shall contain all of the label information required by section 403 of the Federal Food, Drug, and Cosmetic Act (the act), §§ 107.10 and 107.20, and all appropriate sections of part 101 of this chapter, except that the labels of the individual containers contained within the outer package shall be exempt from compliance with the requirements of section 403 (e)(1) and (i)(2) of the act; and §§ 107.10 (a) and (b)(2) and 107.20 (b), (e), and (f), provided that (a) the multiunit package meets all the requirements of this part; (b) individual containers are securely enclosed within and are not intended to be separated

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from the retail package under conditions of retail sale; and (c) the label on each individual container includes the statement ''This Unit Not Intended For Individual Sale'' in type size not less than one-sixteenth inch in height. The word ''Retail'' may be used in lieu of or immediately following the word ''Individual'' in the statement.

Subpart C—Exempt Infant Formulas

§ 107.50 Terms and conditions.

(a) *Terms and conditions.* Section 412(f)(1) of the act exempts from the requirements of section 412(a), (b), and (c)(1)(A) of the act infant formulas that are 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, if such formulas comply with regulations prescribed by the Secretary. The regulations in this subpart establish the terms and conditions that a manufacturer must meet with respect to such infant formulas.

(b) *Infant formulas generally available at the retail level.* (1) These exempt infant formulas can generally be purchased from retail store shelves that are readily available to the public. Such formulas are also typically represented and labeled for use to provide dietary management for diseases or conditions that are not clinically serious or life-threatening, even though such formulas may also be represented and labeled for use in clinically serious or life-threatening disorders.

(2) Except as provided in paragraphs (b)(4) and (5) of this section, an infant formula manufacturer shall, with respect to each formula covered by this paragraph, comply with the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act, the quality control procedure requirements of part 106, and the labeling requirements of subpart B of this part.

(3) To retain the exempt status of an infant formula covered by this paragraph, the manufacturer shall submit to the Food and Drug Administration (FDA), at the address specified in paragraph (e)(1) of this section, on or before May 21, 1986, or on or before the 90th day before the first processing of the infant formula for commercial or charitable distribution, whichever occurs later, the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, and a detailed description of the medical conditions for which the infant formula is represented. FDA will review the information under paragraph (d) of this section.

(4) To retain the exempt status of an infant formula covered by this paragraph, when any change in ingredients or processes that may result in an adverse impact on levels of nutrients or availability of nutrients is instituted, the manufacturer shall submit to FDA at the address specified in paragraph (e)(1) of this section, before the first processing of the infant formula, the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, a detailed description of the reformulation and the rationale for the reformulation, a complete description of the change in processing, and a detailed description of the medical conditions for which the infant formula is represented. FDA will review that information under paragraph (d) of this section.

(5) A manufacturer may deviate from the requirements of paragraph (b)(2) of this section only with respect to those specific requirements for which it submits to FDA, at the address specified in paragraph (e)(1) of this section, the medical, nutritional, scientific, or technological rationale (including any appropriate animal or human clinical studies). FDA will review that information under paragraph (d) of this section.

(c) *Infant formulas not generally available at the retail level.* (1) These exempt infant formulas are not generally found on retail shelves for general consumer purchase. Such formulas typically are prescribed by a physician, and must be requested from a pharmacist or are distributed directly to institutions such as hospitals, clinics, and State or Federal agencies. Such formulas are also generally represented and labeled solely to provide dietary management for specific diseases or conditions that are clinically serious or life-threatening

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and generally are required for prolonged periods of time. Exempt infant formulas distributed directly to institutions such as hospitals, clinics, and State or Federal agencies that are of the same formulation as those generally available at the retail level are subject to the requirements of paragraph (b) of this section rather than to the requirements of this paragraph.

(2) Except as provided for in paragraph (c)(5) of this section, an infant formula manufacturer shall, with respect to each formula covered by this paragraph, comply with the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act, and the labeling requirements of subpart B of this part.

(3) Each manufacturer of an infant formula covered by this paragraph shall establish quality control procedures designed to ensure that the infant formula meets applicable nutrient requirements of this section, including any special nutritional characteristics for the specific disorders or conditions for which the formula is represented for use. Each manufacturer shall maintain records of such quality control procedures sufficient to permit a public health evaluation of each manufactured batch of infant formula and shall permit any authorized FDA employee at all reasonable times to have access to and to copy and verify the records referred to in this paragraph.

(4) To retain the exempt status of an infant formula covered by this paragraph, the manufacturer shall submit the information required by paragraphs (b)(3) and (4) of this section.

(5) A manufacturer may deviate from the requirements of paragraph (c)(2) of this section only with respect to those specific requirements for which it submits to FDA, at the address specified in paragraph (e)(1) of this section, the medical, nutritional, scientific, or technological rationale (including any appropriate animal or human clinical studies). FDA will review that information under paragraph (d) of this section.

(6) The requirements of this section do not apply to an infant formula specially and individually prepared for one or more specific infants on a physician's request.

(d) *FDA review of exempt status.* (1) FDA's Center for Food Safety and Applied Nutrition will review information submitted by infant formula manufacturers under paragraph (b) (3), (b) (4), or (c)(4) of this section. On the basis of such review and other information available to the agency, the Center for Food Safety and Applied Nutrition may impose additional conditions on, or modify requirements for, the quality control procedures, nutrient specifications, or labeling of an infant formula, or withdraw a product's exempt status. Such determinations will be made by the Director of the Center for Food Safety and Applied Nutrition.

(2)(i) If after completing its review of all information submitted, the Center for Food Safety and Applied Nutrition concludes that additional or modified quality control, nutrient, or labeling requirements are needed, or that a product's exempt status is withdrawn, the Center for Food Safety and Applied Nutrition will so notify the manufacturer and this notification will specify the reasons therefor. Upon receipt of this notification, the manufacturer has 10 working days to have the decision reviewed under §10.75 by the office of the Commissioner of Food and Drugs. A determination by the Director of the Center for Food Safety and Applied Nutrition that is not appealed becomes a final agency decision.

(ii) After a final decision by the Director or by the office of the Commissioner that a product's exempt status is withdrawn, the manufacturer shall comply with the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act, the quality control requirements of part 106, and the labeling requirements of subpart B of this part.

(iii) The compliance date for the withdrawal of a product's exempt status or the imposition of additional or modified quality control, nutrient, or labeling requirements is 60 calendar days after issuance of the final decision except as otherwise provided for reasons stated in the decision. If the agency determines that a health hazard

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may exist and so notifies the manufacturer, withdrawal of a product's exempt status shall be effective on the date of receipt of notification from the Director of the Center for Food Safety and Applied Nutrition. Additional or modified requirements, or the withdrawal of an exemption, apply only to those formulas that are manufactured after the compliance date. A postponement of the compliance date may be granted for good cause.

(3) FDA may decide that withdrawal of an exemption is necessary when, on the basis of its review under paragraph (d)(1) of this section, it concludes that quality control procedures are not adequate to ensure that the formula contains all required nutrients, that deviations in nutrient levels are not supported by generally accepted scientific, nutritional, or medical rationale, or that deviations from subpart B of this part are not necessary to provide appropriate directions for preparation and use of the infant formula, or that additional labeling information is necessary.

(4) FDA will use the following criteria in determining whether deviations from the requirements of this subpart are necessary and will adequately protect the public health:

(i) A deviation from the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act is necessary to provide an infant formula that is appropriate for the dietary management of a specific disease, disorder, or medical condition;

(ii) For exempt infant formulas subject to paragraph (b) of this section, a deviation from the quality control procedures requirements of part 106 is necessary because of unusual or difficult technological problems in manufacturing the infant formula; and

(iii) A deviation from the labeling requirements of subpart B of this part is necessary because label information, including pictograms and symbols required by those regulations, could lead to inappropriate use of the product.

(e) *Notification requirements.* (1) Information required by paragraphs (b) and (c) of this section shall be submitted to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutrition, Labeling, and Dietary Supplements, Infant Formula and Medical Foods Staff (HFS–850), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740.

(2) The manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(c)(2) of the Federal Food, Drug, and Cosmetic Act) that reasonably supports the conclusion that an exempt infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer may not provide the nutrients required by paragraph (b) or (c) of this section, or when there is an exempt infant formula that may be otherwise adulterated or misbranded and if so adulterated or misbranded presents a risk of human health. This notification shall be made, 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.), contact the Food and Drug Administration Emergency Call Center at 866–300–4374. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, and to the appropriate FDA district office specified in part 5, subpart M of this chapter.

[50 FR 48187, Nov. 22, 1985, as amended at 61 FR 14479, Apr. 2, 1996; 66 FR 17358, Mar. 30, 2001; 66 FR 56035, Nov. 6, 2001; 67 FR 9585, Mar. 4, 2002; 75 FR 32659, June 9, 2010; 79 FR 8074, Feb. 10, 2014]

Subpart D—Nutrient Requirements

§ 107.100 Nutrient specifications.

(a) An infant formula shall contain the following nutrients at a level not less than the minimum level specified and not more than the maximum level specified for each 100 kilocalories of the infant formula in the form prepared for consumption as directed on the container:

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Nutrients	Unit of measurement	Minimum level	Maximum level
Protein	Grams	1.8	4.5
Fat	Do.	3.3	6.0
	Percent calories	30	54
Linoleic acid	Milligrams	300	
	Percent calories	2.7	
Vitamins			
Vitamin A	International Units	250	750
Vitamin D	Do.	40	100
Vitamin E	Do.	0.7	
Vitamin K	Micrograms	4	
Thiamine (Vitamin B_1)	Do.	40	
Riboflavin (Vitamin B_2)	Do.	60	
Vitamin B_6	Do.	35	
Vitamin B_{12}	Do.	0.15	
Niacin[1]	Do.	250	
Folic acid (Folacin)	Do.	4	
Pantothenic acid	Do.	300	
Biotin[2]	Do.	1.5	
Vitamin C (Ascorbic acid)	Milligrams	8	
Choline[2]	Do.	7	
Inositol[2]	Do.	4	
Minerals			
Calcium	Do.	60	
Phosphorus	Do.	30	
Magnesium	Do.	6	
Iron	Do.	0.15	3.0
Zinc	Do.	0.5	
Manganese	Micrograms	5	
Copper	Do.	60	
Iodine	Do.	5	75
Selenium	Do.	2	7
Sodium	Milligrams	20	60
Potassium	Do.	80	200
Chloride	Do.	55	150

[1] The generic term ''niacin'' includes niacin (nicotinic acid) and niacinamide (nicotinamide).
[2] Required only for non-milk-based infant formulas.

(b) Vitamin E shall be present at a level of at least 0.7 International Unit of vitamin E per gram of linoleic acid.

(c) Any vitamin K added shall be in the form of phylloquinone.

(d) Vitamin B_6 shall be present at a level of at least 15 micrograms of vitamin B_6 for each gram of protein in excess of 1.8 grams of protein per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container.

(e) The ratio of calcium to phosphorus in infant formula in the form prepared for consumption as directed on the container shall be no less than 1.1 and not more than 2.0.

(f) Protein shall be present in an amount not to exceed 4.5 grams per 100 kilocalories regardless of quality, and not less than 1.8 grams per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container when its biological quality is equivalent to or better than that of casein. If the biological quality of the protein is less than that of casein, the minimum amount of protein shall be increased proportionately to compensate for its lower biological quality. For example, an infant formula containing protein with a biological quality of 75 percent of casein shall contain at least 2.4 grams of protein (1.8/0.75). No protein with a biological quality less than 70 percent of casein shall be used.

[50 FR 45108, Oct. 30, 1985, as amended at 80 FR 35841, June 23, 2015]

Subpart E—Infant Formula Recalls

SOURCE: 54 FR 4008, Jan. 27, 1989, unless otherwise noted.

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§ 107.200 Food and Drug Administration-required recall.

When the Food and Drug Administration determines that an adulterated or misbranded infant formula presents a risk to human health, a manufacturer shall immediately take all actions necessary to recall that formula, extending to and including the retail level, consistent with the requirements of this subpart.

§ 107.210 Firm-initiated product removals.

(a) If a manufacturer has determined to recall voluntarily from the market an infant formula that is not subject to § 107.200 but that otherwise violates the laws and regulations administered by the Food and Drug Administration (FDA) and that would be subject to legal action, the manufacturer, upon prompt notification to FDA, shall administer such voluntary recall consistent with the requirements of this subpart.

(b) If a manufacturer has determined to withdraw voluntarily from the market an infant formula that is adulterated or misbranded in only a minor way and that would not be subject to legal action, such removal from the market is deemed to be a market withdrawal, as defined in § 7.3(j) of this chapter. As required by § 107.240(a), the manufacturer shall promptly notify FDA of such violative formula and may, but is not required to, conduct such market withdrawal consistent with the requirements of this subpart pertaining to product recalls.

§ 107.220 Scope and effect of infant formula recalls.

(a) The requirements of this subpart apply:

(1) When the Food and Drug Administration has determined that it is necessary to remove from the market a distributed infant formula that is in violation of the laws and regulations administered by the Food and Drug Administration and that poses a risk to human health; or

(2) When a manufacturer has determined that it is necessary to remove from the market a distributed infant formula that:

(i) Is no longer subject to the manufacturer's control;

(ii) Is in violation of the laws and regulations administered by the Food and Drug Administration and against which the agency could initiate legal or regulatory action; and

(iii) Does not present a human risk.

(b) The Food and Drug Administration will monitor continually the recall action and will take appropriate actions to ensure that the violative infant formula is removed from the market.

§ 107.230 Elements of an infant formula recall.

A recalling firm shall conduct an infant formula recall with the following elements:

(a) The recalling firm shall evaluate in writing the hazard to human health associated with the use of the infant formula. This health hazard evaluation shall include consideration of any disease, injury, or other adverse physiological effect that has been or that could be caused by the infant formula and of the seriousness, likelihood, and consequences of the diseases, injury, or other adverse physiological effect. The Food and Drug Administration will conduct its own health hazard evaluation and promptly notify the recalling firm of the results of that evaluation if the criteria for recall under § 107.200 have been met.

(b) The recalling firm shall devise a written recall strategy suited to the individual circumstances of the particular recall. The recall strategy shall take into account the health hazard evaluation and specify the following: The extent of the recall; if necessary, the public warning to be given about any hazard presented by the infant formula; the disposition of the recalled infant formula; and the effectiveness checks that will be made to determine that the recall is carried out.

(c) The recalling firm shall promptly notify each of its affected direct accounts about the recall. The format of a recall communication shall be distinctive, and the content and extent of a recall communication shall be commensurate with the hazard of the infant formula being recalled and the strategy developed for the recall. The

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recall communication shall instruct consignees to report back quickly to the recalling firm about whether they are in possession of the recalled infant formula and shall include a means of doing so. The recalled communication shall also advise consignees how to return the recall infant formula to the manufacturer or otherwise dispose of it. The recalling firm shall send a followup recall communication to any consignee that does not respond to the initial recall communication.

(d) If the infant formula presents a risk to human health, the recalling firm shall request that each establishment, at which such infant formula is sold or available for sale, post at the point of purchase of such formula a notice of such recall at such establishment. The notice shall be provided by the recalling firm after approval of the notice by the Food and Drug Administration. The recalling firm shall also request that each retail establishment maintain such notice on display until such time as the Food and Drug Administration notifies the recalling firm that the agency considers the recall completed.

(e) The recalling firm shall furnish promptly to the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter, as they are available, copies of the health hazard evaluation, the recall strategy, and all recall communications (including, for a recall under § 107.200, the notice to be displayed at retail establishments) directed to consignees, distributors, retailers, and members of the public.

[54 FR 4008, Jan. 27, 1989, as amended at 66 FR 17358, Mar. 30, 2001; 69 FR 17291, Apr. 2, 2004]

§ 107.240 Notification requirements.

(a) *Telephone report.* When a determination is made that an infant formula is to be recalled, the recalling firm shall telephone within 24 hours the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter and shall provide relevant information about the infant formula that is to be recalled.

(b) *Initial written report.* Within 14 days after the recall has begun, the recalling firm shall provide a written report to the appropriate FDA district office. The report shall contain relevant information, including the following cumulative information concerning the infant formula that is being recalled:

(1) Number of consignees notified of the recall and date and method of notification, including recalls required by § 107.200, information about the notice provided for retail display, and the request for its display.

(2) Number of consignees responding to the recall communication and quantity of recalled infant formula on hand at each consignee at the time the communication was received.

(3) Quantity of recalled infant formula returned or corrected by each consignee contacted and the quantity of recalled infant formula accounted for.

(4) Number and results of effectiveness checks that were made.

(5) Estimated timeframes for completion of the recall.

(c) *Status reports.* The recalling firm shall submit to the appropriate FDA district office a written status report on the recall at least every 14 days until the recall is terminated. The status report shall describe the steps taken by the recalling firm to carry out the recall since the last report and the results of these steps.

[79 FR 8074, Feb. 10, 2014]

§ 107.250 Termination of an infant formula recall.

The recalling firm may submit a recommendation for termination of the recall to the appropriate FDA district office for transmittal to the Recall Coordinator, Division of Enforcement (HFS–605), Office of Compliance, Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740, or by email to *CFSAN.RECALL@fda.hhs.gov*, for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The Agency will respond within 15 days of receipt by the Division of Enforcement of the request for termination. The recalling firm shall

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continue to implement the recall strategy until it receives final written notification from the Agency that the recall has been terminated. The Agency will send such notification, unless the Agency has information from FDA's own audits or from other sources demonstrating that the recall has not been effective. The Agency may conclude that a recall has not been effective if:

(a) The recalling firm's distributors have failed to retrieve the recalled infant formula; or

(b) Stocks of the recalled infant formula remain in distribution channels that are not in direct control of the recalling firm.

[54 FR 4008, Jan. 27, 1989, as amended at 61 FR 14479, Apr. 2, 1996; 66 FR 17359, Mar. 30, 2001; 69 FR 17291, Apr. 2, 2004; 79 FR 8075, Feb. 10, 2014]

§ 107.260 Revision of an infant formula recall.

If after a review of the recalling firm's recall strategy or periodic reports or other monitoring of the recall, the Food and Drug Administration concludes that the actions of the recalling firm are deficient, the agency shall notify the recalling firm of any serious deficiency. The agency may require the firm to:

(a) Change the extent of the recall, if the agency concludes on the basis of available data that the depth of the recall is not adequate in light of the risk to human health presented by the infant formula.

(b) Carry out additional effectiveness checks, if the agency's audits, or other information, demonstrate that the recall has not been effective.

(c) Issue additional notifications to the firm's direct accounts, if the agency's audits, or other information demonstrate that the original notifications were not received, or were disregarded in a significant number of cases.

§ 107.270 Compliance with this subpart.

A recalling firm may satisfy the requirements of this subpart by any means reasonable calculated to meet the obligations set forth in this Subpart E. The recall guidance in subpart C of part 7 of this chapter specify procedures that may be useful to a recalling firm in determining how to comply with these regulations.

[54 FR 4008, Jan. 27, 1989, as amended at 65 FR 56479, Sept. 19, 2000]

§ 107.280 Records retention.

Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls of the formula. Such records shall be retained for at least 1 year after the expiration of the shelf life of the infant formula.

[54 FR 4008, Jan. 27, 1989, as amended at 67 FR 9585, Mar. 4, 2002]

PART 108—EMERGENCY PERMIT CONTROL

Subpart A—General Provisions

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AUTHORITY: 21 U.S.C. 342, 344, 371.

SOURCE: 42 FR 14334, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 108 appear at 81 FR 49896, July 29, 2016.

Subpart A—General Provisions

§ 108.3 Definitions.

(a) The definitions contained in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part.

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