

nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener, e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) "*Low calorie*" foods. A food purporting to be "low calorie" must comply with the criteria set forth for such foods in §101.60(b)(2) and (b)(3) of this chapter.

(d) "*Reduced calorie*" foods and other comparative calorie claims. A food purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such food in §101.60(b)(4) and (b)(5) of this chapter.

(e) *Label terms suggesting usefulness as low calorie or reduced calorie foods.* (1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, and in §101.13(q)(2) of this chapter for soft drinks, a food may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false and misleading, and the food is labeled "low calorie" or "reduced calorie" or bears another comparative calorie claim in compliance with part 101 of this chapter and this section.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term "diet" that clearly shows that the food is offered solely for a dietary use other than regulating body weight, e.g., "for low-sodium diets."

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other food that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) "*Sugar free*," and "*no added sugar*." Criteria for the use of the terms "sugar free" and "no added sugar" are provided for in §101.60(c) of this chapter.

[58 FR 2430, Jan. 6, 1993]

Subpart C [Reserved]

Subpart D—Standards of Identity [Reserved]

PART 106—INFANT FORMULA QUALITY CONTROL PROCEDURES

Subpart A—General Provisions

Sec.

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- 106.120 New formulations and reformulations.

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

SOURCE: 47 FR 17025, Apr. 20, 1982, unless otherwise noted.

Subpart A—General Provisions

§106.1 Status and applicability of the quality control procedures regulation.

(a) The criteria set forth in §§106.20, 106.25, 106.30, 106.90, and 106.100 shall apply in determining whether an infant formula meets the safety, quality, and nutrient requirements of section 412 of the act and the requirements of regulations promulgated under section 412(a)(2) of the act.

(b) The failure to comply with any regulation set forth in §§106.20, 106.25, 106.30, 106.90, and 106.100 applicable to the manufacturing, processing, and packaging of an infant formula shall render such formula adulterated under section 412(a)(1)(C) of the act.

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

§ 106.3 Definitions.

The definitions and interpretations contained in section 201 of the act are applicable to such terms when used in this part. The following definitions shall also apply:

(a) *Indicator nutrient.* An indicator nutrient is a nutrient whose concentration is measured during the manufacture of an infant formula to confirm complete addition and/or uniform distribution of a premix or other substance of which the indicator nutrient is a part.

(b) *In-process batch.* An in-process batch is a combination of ingredients at any point in the manufacturing process before packaging.

(c) *Manufacturer.* A manufacturer is a person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula and/or packages the product in a container for distribution.

(d) *Nutrient.* A nutrient is any vitamin, mineral, or other substance required in accordance with the table set out in section 412(g) of the act or by regulations promulgated under section 412(a)(2)(A) of the act.

(e) *Nutrient premix.* A nutrient premix is a combination of ingredients containing two or more nutrients. A nutrient premix either may be received from a supplier or be prepared by an infant formula manufacturer.

Subpart B—Quality Control Procedures for Assuring Nutrient Content of Infant Formulas

§ 106.20 Ingredient control.

(a) Except as provided in § 106.20(b), no analysis before use in manufacturing is needed for ingredients that are generally stable in shipping and storage, and that either are received under a supplier's guarantee or certification that the mixture has been analyzed as to nutrient composition or are labeled as having nutrient compositions complying with specifications in the U.S. Pharmacopoeia, the National Formulary, the Food Chemicals Codex, or other similar recognized standards.

(b) Unless each batch of finished product is analyzed as specified in § 106.30(b)(1) before release of product

for commercial or charitable distribution, the following shall apply:

(1) When an ingredient is relied upon as a source of a nutrient(s) and when evidence indicates that such nutrient(s) in that ingredient is likely to be affected adversely by shipping or storage conditions, the manufacturer shall analyze that ingredient for each relied-upon nutrient that may be affected, using validated analytical methods.

(2) Ingredients, including nutrient premixes, that are either without a supplier's guarantee or certification, or not labeled as complying with prescribed standards, shall be sampled and analyzed for each relied-upon nutrient by the manufacturer, except that ingredients used as a major source of protein or fat need not be analyzed for each relied-upon nutrient if the manufacturer has records to show that each relied-upon nutrient is present at a reasonably constant level. Nutrient premixes prepared by the infant formula manufacturer shall be sampled and analyzed for each relied-upon nutrient. Nutrient premixes which are received from suppliers shall be sampled and analyzed for each relied-upon nutrient unless the supplier has sampled and analyzed each batch of premix for each relied-upon nutrient and has so certified in writing.

§ 106.25 In-process control.

(a) For each infant formula, a master manufacturing order shall be prepared and approved by a responsible official of the manufacturer. The manufacturer shall establish a quality control system that assures and verifies the addition of each ingredient specified in the manufacturing order.

(b) Unless each batch of finished product is analyzed as specified in § 106.30(b)(1), the manufacturer shall analyze each in-process batch for:

- (1) Solids;
- (2) Protein, fat, and carbohydrates (carbohydrates either by analysis or by mathematical difference);
- (3) The indicator nutrient(s) in each nutrient premix;

(4) Each nutrient added independently of nutrient premixes during formulation of the product, except for linoleic acid, vitamin D, vitamin K, choline, inositol, and biotin; and

(5) Solids or an appropriate nutrient to confirm proper dilution when final dilution is made after performance of the analyses in paragraph (b) (1) through (4) of this section.

§ 106.30 Finished product evaluation.

(a) The manufacturer shall establish criteria for sampling and testing to ensure that each batch of infant formula meets the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act before release of product for commercial or charitable distribution.

(b)(1) *Immediate analysis.* Before release of product for commercial or charitable distribution, the manufacturer shall analyze representative samples of each batch of finished product for:

(i) Specific nutrient(s) to assess process degradation; and

(ii) All nutrients not previously analyzed for by the manufacturers, unless each in-process batch is analyzed for nutrients as specified in § 106.25(b) and the ingredients are analyzed as specified in § 106.20(b). No analyses are needed for linoleic acid, vitamin D, vitamin K, choline, inositol, and biotin; and for nutrients that are added as a part of a nutrient premix analyzed by the manufacturer or having a supplier's guarantee or certification and for which an indicator nutrient(s) was analyzed by the manufacturer.

(2) *Periodic analysis.* The manufacturer shall sample at least one newly processed finished product batch every 3 months and shall analyze representative samples for all nutrients except those that the manufacturers measured in the immediate analysis of that product batch.

(3) *Stability analysis.* Using representative samples collected from finished product batches, the manufacturer shall conduct stability analysis for selected nutrients with sufficient frequency to substantiate the maintenance of nutrient content throughout the shelf life of the product.

(c) The manufacturer shall evaluate new formulations and the effect of changes in ingredients or processing conditions that could affect the level of nutrients by means of a testing pro-

gram designed to confirm uniformity of batches and to determine the effects of such changes. The following shall apply:

(1) A minor change is a minor reduction in nutrient levels, a minor increase in levels of nutrients that are subject to maximum limits established under section 412(g) of the act or in regulations established under section 412(a)(2) of the act, or any other change where experience or theory would not predict a possible significant adverse impact on nutrient levels or nutrient availability. After a minor change the manufacturer shall analyze representative samples for all nutrients so changed and those possibly affected by the change.

(2) A major change is any new formulation, or any change of ingredients or processes where experience or theory would predict a possible significant adverse impact on levels of nutrients or availability of nutrients. After a major change the manufacturer shall analyze representative samples for osmolality, all nutrients, and the biological quality of the protein. A protein biological quality analysis is not necessary for a formulation change that is not expected to have an adverse effect on the biological quality of the protein. Vitamin D shall be determined by the rat bioassay method as prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC), 13th Ed. (1980), sections 43.195-43.208, "Vitamin D (30)—Official Final Action," which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Before release of the product for commercial or charitable distribution, the manufacturer shall have completed all appropriate analyses except that shipment of the product need not be delayed until results of the vitamin D bioassay and, if required, a protein biological quality bioassay are complete, provided such bioassays have been initiated, and if another analysis for the vitamin D has been run and the protein content has

been determined by a suitable method. The biological quality of the protein shall be determined by an appropriate modification of the AOAC bioassay method of analysis. The manufacturer shall analyze additional samples from the same batch for vitamin D, by any suitable method, and for the biological quality of the protein. The manufacturer shall perform such analyses at least annually for a period not to exceed the expected shelf life of the product.

(d) A simple adjustment in the level of an ingredient to accommodate inconsistencies in processing is considered to be neither a minor nor a major change.

[47 FR 17025, Apr. 20, 1982, as amended at 54 FR 24891, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

§ 106.90 Coding.

The manufacturer shall code all infant formulas in conformity with the coding requirements that are applicable to thermally processed low-acid foods packaged in hermetically sealed containers as prescribed in § 113.60(c).

Subpart C—Records and Reports

§ 106.100 Records.

(a) Every manufacturer of infant formula shall maintain the records specified in this regulation in order to permit the Food and Drug Administration to determine whether each manufacturer is in compliance with section 412 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The manufacturer shall maintain all records that pertain to food-packaging materials subject to § 174.5 of this chapter and that bear on whether such materials would cause an infant formula to be adulterated within the meaning of section 402(a)(2)(C) of the act.

(c) The manufacturer shall maintain all records that pertain to nutrient premix testing that it generates or receives. Such records shall include, but are not limited to:

(1) Any results of testing conducted to ensure that each nutrient premix is in compliance with the premix certificate and guarantee and specifications that have been provided to the manu-

facturer by the premix supplier, including tests conducted when nutrients exceed their expiration date or shelf life (retest date).

(2) All certificates and guarantees given by premix suppliers concerning the nutrients required by section 412(i) of the act and § 107.100 of this chapter.

(d) The premix supplier shall maintain the results of all testing conducted to provide all certificates and guarantees concerning nutrient premixes for infant formulas. Such records shall include but are not limited to:

(1) The results of tests conducted to determine the purity of each nutrient required by section 412(i) of the act or § 107.100 of this chapter and any other nutrient listed in the certificate and guarantee;

(2) The weight of each nutrient added;

(3) The results of any quantitative tests conducted to determine the amount of each nutrient certified or guaranteed; and

(4) The results of any quantitative tests conducted to identify the nutrient levels present when nutrient premixes exceed their expiration date or shelf life (retest date).

(e) The manufacturer shall maintain all records necessary to ensure proper nutrient quality control in the manufacture of infant formula products. Such records shall include the results of any testing conducted to verify that each nutrient required by section 412(i) of the act or § 107.100 of this chapter is present in each batch of infant formula at the appropriate concentration. This requirement pertains to ingredients, in process batch and finished product from the time of manufacture through its expiration date.

(f) The manufacturer shall maintain all records necessary to ensure required nutrient content at the final product stage. Such records shall include, but are not limited to, testing results for vitamins A, B₁ (thiamine), C, and E for each batch of infant formula. "Final product stage" means the point in the manufacturing process prior to distribution at which the infant formula is homogenous and not subject to further degradation from the manufacturing process.

(g) The manufacturer shall maintain all records pertaining to distribution of the infant formula. Such records shall include, but not be limited to, all information and data necessary to effect and monitor recalls of the manufacturer's infant formula products in accordance with subpart E of part 107 of this chapter.

(h) The manufacturer shall maintain all records pertaining to the microbiological quality and purity of raw materials and finished powdered infant formula.

(i) [Reserved]

(j) The manufacturer shall maintain all records pertaining to regularly scheduled audits, including audit plans and procedures. Audit plans identify the specific manufacturing and quality control procedures to be reviewed. Audit procedures are the methods used to review the manufacturing and quality control procedures. Records of audits shall include the information and data necessary for a determination as to whether the manufacturer complies with the current good manufacturing practices and quality procedures identified in parts 106, 107, 109, 110, and 113 of this chapter. The records shall include written assurances from the manufacturer that regularly scheduled audits are being conducted by appropriately trained individuals who do not have any direct responsibility for the manufacture or production of infant formula, and that the complete audit plans and procedures for the firm have been followed. The actual written reports of the audits need not be made available.

(k) The manufacturer shall maintain procedures describing how all written and oral complaints regarding infant formula will be handled. The manufacturer shall follow these procedures and shall include in them provisions for the review of any complaint involving an infant formula and for determining the need for an investigation of the possible existence of a hazard to health.

(1) For purposes of this section, every manufacturer shall interpret a "complaint" as any communication that contains any allegation, written or oral, expressing dissatisfaction with a product for any reason, including concerns about the possible existence of a

hazard to health and about appearance, taste, odor, and quality. Correspondence about prices, package size or shape, or other matters that could not possibly reveal the existence of a hazard to health shall not, for compliance purposes, be considered a complaint and therefore need not be made available to an FDA investigator.

(2) When a complaint shows that a hazard to health possibly exists, the manufacturer shall conduct an investigation into the validity of the complaint. Where such an investigation is conducted, the manufacturer shall include in its file on the complaint the determination as to whether a hazard to health exists and the basis for that determination. No investigation is necessary when the manufacturer determines that there is no possibility of a hazard to health. When no investigation is necessary, the manufacturer shall include in the record the reason that an investigation was found to be unnecessary and the name of the responsible person making that determination.

(3) When there is a reasonable possibility of a causal relationship between the consumption of an infant formula and an infant's death, the manufacturer shall, within 15 days of receiving such information, conduct an investigation and notify the agency as required in § 106.120(b).

(4) The manufacturer shall maintain in designated files all records pertaining to the complaints it receives. The manufacturer shall separate the files into two classes:

(i) Those complaints that allege that the infant became ill from consuming the product or required treatment by a physician or health-care provider.

(ii) Those complaints that may involve a possible existence of a hazard to health but do not refer to an infant becoming ill or the need for treatment by physician or a health care provider.

(5) The manufacturer shall include in a complaint file the following information concerning the complaint:

- (i) The name of the infant formula;
- (ii) The batch number;
- (iii) The name of complainant;
- (iv) A copy of the complaint or a memo of the telephone conversation or

meeting and all correspondence with the complainant;

(v) By reference or copy, all the associated manufacturing records and complaint investigation records needed to evaluate the complaint. When copies of such records are not maintained in the complaint file, they must be available within 24 hours when requested by an FDA official.

(vi) All actions taken to follow up on the complaint; and

(vii) All findings and evaluations of the complaint.

(6) The manufacturer should maintain the files regarding infant formula complaints at the establishment where the infant formula was manufactured, processed, or packed. When the manufacturer wishes to maintain all consumer complaints for the entire firm at one location other than at the facility where an infant formula was manufactured, processed, or packed, the manufacturer may do so as long as all records required by this section are available within 24 hours of request for inspection at that facility. However, all records of consumer complaints, including summaries, any reports, and any files, maintained at the manufacturing facility or at any other facility shall be made available to investigators for review and copying upon request.

(l) The manufacturer shall make readily available for authorized inspection all records required under this part or copies of such records. Records shall be available at any reasonable time at the establishment where the activities described in such records occurred. (Infant formula complaint files may be maintained at one facility, as provided in § 106.100(k)(6), if all required records are readily available at that facility.) These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by electronic means shall be considered as meeting the requirements of this paragraph.

(m) Records required under this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original

records. Where reduction techniques, such as microfilming are used, suitable reader and photocopying equipment shall be readily available.

(n) Production control, product testing, testing results, complaints, and distribution records necessary to verify compliance with parts 106, 107, 109, 110, and 113 of this chapter, or with other appropriate regulations, shall be retained for 1 year after the expiration of the shelf life of the infant formula or 3 years from the date of manufacture, whichever is greater.

(o) The manufacturer shall maintain quality control records that contain sufficient information to permit a public health evaluation of any batch of infant formula.

[56 FR 66571, Dec. 24, 1991; 57 FR 7435, Mar. 2, 1992]

Subpart D—Notification Requirements

§ 106.120 New formulations and reformulations.

(a) Information required by section 412(b)(2) and (3) of the act shall be submitted to Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(b) The manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(c)(2) of the act) that reasonably supports the conclusion that an 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 section 412(g) of the act and by regulations promulgated under section 412(a)(2) of the act, or when there is an infant formula that is otherwise adulterated or misbranded and that may present risk to human health. This notification shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office specified in § 5.215 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, 200 C St. SW., Washington, DC 20204, and to the appropriate Food and Drug Administration district office specified in § 5.215.

[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]

PART 107—INFANT FORMULA

Subpart A—General Provisions

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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.
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.

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