Food and Drug Administration, HHS

§ 105.3

(a) The term "special dietary uses," as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(1) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(2) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(3) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of the nutritional status of the consumer or the proportions in which the food is consumed.

(b) The term "average serving" shall be one entire frozen "heat and serve" dinner.

(4) For the purposes of labeling, an "average serving" shall be one entire frozen "heat and serve" dinner.

[42 FR 14327, Mar. 5, 1977]

PART 105—FOODS FOR SPECIAL DIETARY USE

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Subpart A—General Provisions

§ 105.3 Definitions and interpretations.

The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (hereafter "the act") shall be applicable with the following additions:

(a)(1) The term special dietary uses, as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(i) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(ii) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(iii) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of the nutritional status of the consumer or the proportions in which the food is consumed.

(2) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(b) The term "average serving" shall be one entire frozen "heat and serve" dinner.

(4) For the purposes of labeling, an "average serving" shall be one entire frozen "heat and serve" dinner.

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of whether such food also purports to be or is represented for general use.

(2) The use of an artificial sweetener in a food, except when specifically and solely used for achieving a physical characteristic in the food which cannot be achieved with sugar or other nutritive sweetener, shall be considered a use for regulation of the intake of calories and available carbohydrate, or for use in the diets of diabetics and is therefore a special dietary use.

(b)–(d) [Reserved]

(e) For the purposes of the regulations in this part, the terms infant, child, and adult mean persons not more than 12 months old, more than 12 months but less than 12 years old, and 12 years or more old, respectively.

§ 105.65 Infant foods.

(a) If a food (other than a dietary supplement of vitamins and/or minerals alone) purports to be or is represented for special dietary use for infants, the label shall bear, if such food is fabricated from two or more ingredients, the common or usual name of each ingredient, including spices, flavoring, and coloring.

(b) If such food, or any ingredient thereof, consists in whole or in part of plant or animal matter and the name of such food or ingredient does not clearly reveal the specific plant or animal which is its source, such name shall be so qualified as to reveal clearly the specific plant or animal that is such source.

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.

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