

[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2006]
[CITE: 21CFR105]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION PART 105 FOODS FOR
SPECIAL DIETARY USE

Subpart A--General Provisions

Sec. 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 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.

[42 FR 14328, Mar. 15, 1977, as amended at 44 FR 16006, Mar. 16, 1979; 44 FR 49665, Aug. 24, 1979]

Subpart B--Label Statements

Sec. 105.62 Hypoallergenic foods.

If a food purports to be or is represented for special dietary use by reason of the decrease or absence of any allergenic property or by reason of being offered as food suitable as a substitute for another food having an allergenic property, the label shall bear:

(a) The common or usual name and the quantity or proportion of each ingredient (including spices, flavoring, and coloring) in case the food is fabricated from two or more ingredients.

(b) A qualification of the name of the food, or the name of each ingredient thereof in case the food is fabricated from two or more ingredients, to reveal clearly the specific plant or animal that is the source of such food or of such ingredient, if such food or such ingredient consists in whole or in part of plant or animal matter and such name does not reveal clearly the specific plant or animal that is such a source.

(c) An informative statement of the nature and effect of any treatment or processing of the food or any ingredient thereof, if the changed allergenic property results from such treatment or processing.

Sec. 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.

[42 FR 14328, Mar. 15, 1977, as amended at 47 FR 947, Jan. 8, 1982; 49 FR 10090, Mar. 19, 1984; 50 FR 1840, Jan. 14, 1985]

Sec. 105.66 Label statements relating to usefulness in reducing or maintaining body weight.

(a) General requirements. Any food that purports to be or is represented for special dietary use because of usefulness in reducing or maintaining body weight shall bear:

(1) Nutrition labeling in conformity with 101.9, or, where applicable, 101.36 of this chapter, unless exempt under that section; and

(2) A conspicuous statement of the basis upon which the food claims to be of special dietary usefulness.

(b) Nonnutritive ingredients. (1) Any food subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary food may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the food under the applicable law and regulations of this chapter. Any food that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as 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]

Authority: 21 U.S.C. 321, 341, 343, 348, 350, 371, 379e.

Source: 42 FR 14328, Mar. 15, 1977, unless otherwise noted.