

## § 101.65

## 21 CFR Ch. I (4–1–04 Edition)

contain more than 19.5 g of total fat per labeled serving:

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference food it resembles as defined in §101.13(j)(1) and for which it substitutes as specified in §101.13(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share.

(B) The food contains 2 g or less of saturated fatty acids per 100 g;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding any disclosure statement required under §101.13(h) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in §101.13(j)(2) for relative claims:

(1) The identity of the reference food and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., 25 percent less cholesterol than \_\_\_\_\_); and

(2) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference food that it replaces (e.g., “Cholesterol lowered from 30 mg to 22 mg per 3 oz of product.”) is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with §101.2.

(iii) Claims described in paragraph (d)(5) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for “low cholesterol.”

(e) “Lean” and “extra lean” claims. (1) The term “lean” may be used on the

label or in labeling of foods except meal products as defined in §101.13(l) and main dish products as defined in §101.13(m) provided that the food is a seafood or game meat product and as packaged contains less than 10 g total fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g;

(2) The term defined in paragraph (e)(1) of this section may be used on the label or in the labeling of meal products as defined in §101.13(l) or main dish products as defined in §101.13(m) provided that the food contains less than 10 g total fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per 100 g and per labeled serving;

(3) The term “extra lean” may be used on the label or in the labeling of foods except meal products as defined in §101.13(l) and main dish products as defined in §101.13(m) provided that the food is a discrete seafood or game meat product and as packaged contains less than 5 g total fat, less than 2 g saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g; and

(4) The term defined in paragraph (e)(3) of this section may be used on the label or in labeling of meal products as defined in §101.13(l) and main dish products as defined in §101.13(m) provided that the food contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g and per labeled serving.

(f) *Misbranding.* Any label or labeling containing any statement concerning fat, fatty acids, or cholesterol that is not in conformity with this section shall be deemed to be misbranded under sections 201(n), 403(a), and 403(r) of the Federal Food, Drug, and Cosmetic Act.

[58 FR 2413, Jan. 6, 1993; 58 FR 17342, 17343, Apr. 2, 1993, as amended at 58 FR 44032, Aug. 18, 1993; 58 FR 60105, Nov. 15, 1993; 59 FR 394, Jan. 4, 1994; 60 FR 17207, Apr. 5, 1995; 61 FR 59001, Nov. 20, 1996; 63 FR 26980, May 15, 1998]

### § 101.65 Implied nutrient content claims and related label statements.

(a) *General requirements.* An implied nutrient content claim can only be made on the label and in labeling of the food if:

(1) The claim uses one of the terms described in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9, § 101.10, or § 101.36, as applicable.

(b) *Label statements that are not implied claims.* Certain label statements about the nature of a product are not nutrient content claims unless such statements are made in a context that would make them an implied claim under § 101.13(b)(2). The following types of label statements are generally not implied nutrient content claims and, as such, are not subject to the requirements of § 101.13 and this section:

(1) A claim that a specific ingredient or food component is absent from a product, provided that the purpose of such claim is to facilitate avoidance of the substances because of food allergies (see § 105.62 of this chapter), food intolerance, religious beliefs, or dietary practices such as vegetarianism or other nonnutrition related reason, e.g., "100 percent milk free;"

(2) A claim about a substance that is nonnutritive or that does not have a nutritive function, e.g., "contains no preservatives," "no artificial colors;"

(3) A claim about the presence of an ingredient that is perceived to add value to the product, e.g., "made with real butter," "made with whole fruit," or "contains honey," except that claims about the presence of ingredients other than vitamins or minerals or that are represented as a source of vitamins and minerals are not allowed on labels or in labeling of dietary supplements of vitamins and minerals that are not in conventional food form.

(4) A statement of identity for a food in which an ingredient constitutes essentially 100 percent of a food (e.g., "corn oil," "oat bran," "dietary supplement of vitamin C 60 mg tablet").

(5) A statement of identity that names as a characterizing ingredient, an ingredient associated with a nutrient benefit (e.g., "corn oil margarine," "oat bran muffins," or "whole wheat bagels"), unless such claim is made in a context in which label or labeling statements, symbols, vignettes, or

other forms of communication suggest that a nutrient is absent or present in a certain amount; and

(6) A label statement made in compliance with a specific provision of part 105 of this chapter, solely to note that a food has special dietary usefulness relative to a physical, physiological, pathological, or other condition, where the claim identifies the special diet of which the food is intended to be a part.

(c) *Particular implied nutrient content claims.* (1) Claims about the food or an ingredient therein that suggest that a nutrient or an ingredient is absent or present in a certain amount (e.g., "high in oat bran") are implied nutrient content claims and must comply with paragraph (a) of this section.

(2) The phrases "contains the same amount of [nutrient] as a [food]" and "as much [nutrient] as a [food]" may be used on the label or in the labeling of foods, provided that the amount of the nutrient in the reference food is enough to qualify that food as a "good source" of that nutrient, and the labeled food, on a per serving basis, is an equivalent, good source of that nutrient (e.g., "as much fiber as an apple," "Contains the same amount of Vitamin C as an 8 oz glass of orange juice.").

(3) Claims may be made that a food contains or is made with an ingredient that is known to contain a particular nutrient, or is prepared in a way that affects the content of a particular nutrient in the food, if the finished food is either "low" in or a "good source" of the nutrient that is associated with the ingredient or type of preparation. If a more specific level is claimed (e.g., "high in \_\_\_\_\_"), that level of the nutrient must be present in the food. For example, a claim that a food contains oat bran is a claim that it is a good source of dietary fiber; that a food is made only with vegetable oil is a claim that it is low in saturated fat; and that a food contains no oil is a claim that it is fat free.

(d) *General nutritional claims.* (1) Claims about a food that suggest that the food because of its nutrient content may be useful in maintaining healthy dietary practices and that are made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams of fat") are

implied nutrient content claims covered by this paragraph.

(2) The term “healthy” or any derivative of the term “healthy,” such as “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness” may be used on the label or in labeling of a food, other than raw, single ingredient seafood or game meat products, main dish products as defined in §101.13(m), and meal products as defined in §101.13(l), as an implied nutrient content claim to denote foods that are useful in constructing a diet that is consistent with dietary recommendations provided that:

(i) The food meets the definition of “low” for fat and saturated fat;

(ii)(A) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and, before January 1, 1998, contains 480 milligrams (mg) sodium or less per reference amount customarily consumed, and per labeled serving; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and, before January 1, 1998, contains 480 mg sodium or less per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount as defined in §101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the “as prepared” form);

(C)(1) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and, after January 1, 1998, contains 360 mg sodium or less per reference amount customarily consumed, and per labeled serving; or

(2) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and, after January 1, 1998, contains 360 mg sodium or less per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount as defined in §101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the “as prepared” form);

(iii) Cholesterol is not present at a level exceeding the disclosure level as described in §101.13(h);

(iv) The food contains at least 10 percent of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount customarily consumed of vitamin A, vitamin C, calcium, iron, protein, or fiber, except for the following:

(A) Raw fruits and vegetables;

(B) Frozen or canned single ingredient fruits and vegetables and mixtures of frozen or canned single ingredient fruits and vegetables, except that ingredients whose addition does not change the nutrient profile of the fruit or vegetable may be added;

(C) Enriched cereal-grain products that conform to a standard of identity in part 136, 137, or 139 of this chapter.

(v) Where compliance with paragraph (d)(2)(iv) of this section is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in §104.20 of this chapter; and

(vi) The food complies with definitions and declaration requirements established in part 101 of this chapter for any specific nutrient content claim on the label or in labeling.

(3) The term “healthy” or its derivatives may be used on the label or in labeling of raw, single ingredient seafood or game meat as an implied nutrient content claim provided that:

(i) The food contains less than 5 g total fat, less than 2 g saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g;

(ii)(A) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and, before January 1, 1998, contains 480 mg sodium or less per reference amount customarily consumed, and per labeled serving; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and, before January 1, 1998, contains 480 mg sodium or less per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount as defined in §101.9(f)(1), of all nutrients

per reference amount customarily consumed, the per 50 g criterion refers to the "as prepared" form);

(C)(I) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and, after January 1, 1998, contains 360 mg sodium or less per reference amount customarily consumed, and per labeled serving; or

(2) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and, after January 1, 1998, contains 360 mg sodium or less per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount as defined in §101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the "as prepared" form);

(iii) The food contains at least 10 percent of the RDI or DRV per reference amount customarily consumed of vitamin A, vitamin C, calcium, iron, protein, or fiber;

(iv) Where compliance with paragraph (d)(3)(iii) of this section is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in §104.20 of this chapter; and

(v) The food complies with definitions and declaration requirements established in this part for any specific nutrient content claim on the label or in labeling.

(4) The term "healthy" or its derivatives may be used on the label or in labeling of main dish products, as defined in §101.13(m), and meal products, as defined in §101.13(l) as an implied nutrient content claim provided that:

(i) The food meets the definition of "low" for fat and saturated fat;

(ii)(A) Before January 1, 1998, sodium is not present at a level exceeding 600 mg per labeled serving, or

(B) After January 1, 1998, sodium is not present at a level exceeding 480 mg per labeled serving;

(iii) Cholesterol is not present at a level exceeding 90 mg per labeled serving;

(iv) The food contains at least 10 percent of the RDI or DRV per labeled serving of two (for main dish products) or three (for meal products) of the fol-

lowing nutrients—vitamin A, vitamin C, calcium, iron, protein, or fiber;

(v) Where compliance with paragraph (d)(4)(iv) of this section is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in §104.20 of this chapter; and

(vi) The food complies with definitions and declaration requirements established in this part for any specific nutrient content claim on the label or in labeling.

[58 FR 2413, Jan. 6, 1993; 58 FR 17343, Apr. 2, 1993, as amended at 59 FR 394, Jan. 4, 1994; 59 FR 24249, May 10, 1994; 59 FR 50828, Oct. 6, 1994; 62 FR 49858, Sept. 23, 1997; 63 FR 14355, Mar. 25, 1998]

EFFECTIVE DATE NOTE: At 59 FR 24249, May 10, 1994, §101.65 was amended by adding paragraphs (d) (2) through (4). At 62 FR 15391, Apr. 1, 1997, paragraphs (d)(2)(ii)(C) and (d)(4)(ii)(B) were stayed until Jan. 1, 2000. At 64 FR 12887, Mar. 16, 1999, paragraphs (d)(2)(ii)(C), (d)(3)(ii)(C), and (d)(4)(ii)(B) were stayed until Jan. 1, 2003. At 67 FR 30795, May 8, 2002, the stay was extended until Jan. 1, 2006.

#### § 101.67 Use of nutrient content claims for butter.

(a) Claims may be made to characterize the level of nutrients, including fat, in butter if:

(1) The claim complies with the requirements of §101.13 and with the requirements of the regulations in this subpart that define the particular nutrient content claim that is used and how it is to be presented. In determining whether a claim is appropriate, the calculation of the percent fat reduction in milkfat shall be based on the 80 percent milkfat requirement provided by the statutory standard for butter (21 U.S.C. 321a);

(2) The product contains cream or milk, including milk constituents (including, but not limited to, whey, casein, modified whey, and salts of casein), or both, with or without added salt, with or without safe and suitable colorings, with or without nutrients added to comply with paragraph (a)(3) of this section, and with or without safe and suitable bacterial cultures. The product may contain safe and suitable ingredients to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add