(c) Data bases of nutrient values for raw fruits, vegetables, and fish that are not among the 20 most frequently consumed may be used to develop nutrition labeling values for these foods. This includes data bases of nutrient values for specific varieties, species, or cultivars of raw fruits, vegetables, and fish not specifically identified among the 20 most frequently consumed.

1. The food names and descriptions for the fruits, vegetables, and fish should clearly identify these foods as distinct from foods among the most frequently consumed list for which FDA has provided data.


3. Nutrition labeling values computed from data bases are subject to the compliance provisions of §101.9(g).

   (i) Compliance with the provisions of §101.9(g) may be achieved by use of a data base that has been developed following FDA guideline procedures and approved by FDA.

   (A) The submission to FDA for approval should include but need not be limited to information on the following: Source of the data (names of investigators, name of organization, place of analyses, dates of analyses), number of samples, sampling design, analytical methods, statistical treatment of the data, and proposed quantitative label declarations. The values for declaration should be determined in accordance with the "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases."

   (B) FDA approval of a data base and nutrition labeling values shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the data base in writing. Approvals will be in effect for a limited time, e.g., 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices (e.g., a change occurs in a predominant variety produced). FDA will take steps to revoke its approval of the data base and nutrition labeling values if FDA monitoring suggests that the data base or nutrition labeling values are no longer representative of the item sold in this country. Approval requests shall be submitted in accordance with the provisions of §101.30 of this chapter.

   (ii) [Reserved]

Subpart D—Specific Requirements for Nutrient Content Claims

SOURCE: 58 FR 2413, Jan. 6, 1993, unless otherwise noted.

§101.54 Nutrient content claims for “good source,” “high,” “more,” and “high potency.”

(a) General requirements. Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a food in relation to the Reference Daily Intake (RDI) established for that nutrient in §101.9(c)(8)(iv) or Daily Reference Value (DRV) established for that nutrient in §101.9(c)(9), (excluding total carbohydrates) may only be made on the label or in labeling of the food if:

1. The claim uses one of the terms defined 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) “High” claims. (1) The terms “high,” “rich in,” or “excellent source of” may be used on the label and 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 contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

   (i) Compliance with the provisions of §101.9(g) may be achieved by use of a data base that has been developed following FDA guideline procedures and approved by FDA.

   (A) The submission to FDA for approval should include but need not be limited to information on the following: Source of the data (names of investigators, name of organization, place of analyses, dates of analyses), number of samples, sampling design, analytical methods, statistical treatment of the data, and proposed quantitative label declarations. The values for declaration should be determined in accordance with the "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases."

   (B) FDA approval of a data base and nutrition labeling values shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the data base in writing. Approvals will be in effect for a limited time, e.g., 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices (e.g., a change occurs in a predominant variety produced). FDA will take steps to revoke its approval of the data base and nutrition labeling values if FDA monitoring suggests that the data base or nutrition labeling values are no longer representative of the item sold in this country. Approval requests shall be submitted in accordance with the provisions of §101.30 of this chapter.

   (ii) [Reserved]

21 CFR Ch. I (4-1-99 Edition)
(c) “Good Source” claims. (1) The terms “good source,” “contains,” or “provides” may be used on the label and 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 contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label and in the labeling of meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:
   (i) The product contains a food that meets the definition of “good source” in paragraph (c)(1) of this section; and
   (ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., the serving of sweet potatoes in this product is a “good source” of fiber).

(d) “Fiber” claims. (1) If a nutrient content claim is made with respect to the level of dietary fiber, that is, that the product is high in fiber, a good source of fiber, or that the food contains “more” fiber, and the food is not “low” in total fat as defined in §101.62(b)(2) or, in the case of a meal product, as defined in §101.13(l), or main dish product, as defined in §101.13(m), is not “low” in total fat as defined in §101.62(b)(3), then the label shall disclose the level of total fat per labeled serving.

(2) The disclosure shall appear in immediate proximity to such claim, be in a type size no less than one-half the size of the claim and precede any disclosure statement required under §101.13(h) (e.g., “contains [X amount] of total fat per serving. See nutrition information for fat content”).

(e) “More” claims. (1) A relative claim using the terms “more,” “fortified,” “enriched,” and “added” may be used on the label or in labeling of foods to describe the level of protein, vitamins, minerals, dietary fiber, or potassium, except as limited by §101.13(j)(1)(i), in meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:
   (i) The food contains at least 10 percent more of the RDI for vitamins or minerals or of the DRV for protein, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference food; and
   (ii) Where the claim 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
   (iii) As required in §101.13(j)(2) for relative claims:
      (A) The identity of the reference food and the percentage (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., “contains 10 percent more of the Daily Value for fiber than white bread”); and
      (B) Quantitative information comparing the level of the nutrient in the product per labeled serving with that of the reference food that it replaces (e.g., “Fiber content of white bread is 1 gram (g) per serving; (this product) 3.5 g per serving”) 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 §101.22.

(2) A relative claim using the terms “more,” “fortified,” “enriched,” “added,” “extra,” and “plus” may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber or potassium, except as limited in §101.13(j)(1)(i), in meal products as defined in §101.13(l) or main dish products as defined in §101.13(m), provided that:
   (i) The food contains at least 10 percent more of the RDI for vitamins or minerals or of the DRV for protein, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of food than an appropriate reference food.
   (ii) Where the claim 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
   (iii) As required in §101.13(j)(2) for relative claims:
      (A) The identity of the reference food and the percentage (or fraction) that the nutrient was increased relative to
the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., “contains 10 percent more of the Daily Value for fiber per 3 oz than does ‘X brand of product’”), and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., “The fiber content of ‘X brand of product’ is 2 g per 3 oz. This product contains 4.5 g per 3 oz.”) 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.

(f) “High potency” claims.

(1)(i) The term “high potency” may be used on the label or in the labeling of foods to describe individual vitamins or minerals that are present at 100 percent or more of the RDI per reference amount customarily consumed.

(ii) When the term “high potency” is used to describe individual vitamins or minerals in a product that contains other nutrients or dietary ingredients, the label or labeling shall clearly identify which vitamin or mineral is described by the term “high potency” (e.g., “Botanical ‘X’ with high potency vitamin E”).

(2) The term “high potency” may be used on the label or in the labeling of a multiingredient food product to describe the product if the product contains 100 percent or more of the RDI for at least two-thirds of the vitamins and minerals that are listed in §101.9(c)(8)(iv) and that are present in the product at 2 percent or more of the RDI (e.g., “High potency multivitamin, multimineral dietary supplement tablets”).

(3) Where compliance with paragraphs (f)(1)(i), (f)(1)(ii), or (f)(2) of this section is based on a nutrient that has been added to a food (other than a dietary supplement), that fortification shall be in accordance with the policy on fortification of foods in §104.20 of this chapter.

(g) Nutrient content claims using the term “antioxidant.” A nutrient content claim that characterizes the level of antioxidant nutrients present in a food may be used on the label or in the labeling of that food when:

(1) An RDI has been established for each of the nutrients;

(2) The nutrients that are the subject of the claim have recognized antioxidant activity; that is, when there exists scientific evidence that, following absorption from the gastrointestinal tract, the substance participates in physiological, biochemical, or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions;

(3) The level of each nutrient that is the subject of the claim is sufficient to qualify for the §101.54(b), (c), or (e) claim (e.g., to bear the claim “high in antioxidant vitamin C,” the product must contain 20 percent or more of the RDI for vitamin C). Beta-carotene may be a subject of the claim when the level of vitamin A present as beta-carotene in the food that bears the claim is sufficient to qualify for the claim. For example, for the claim “good source of antioxidant beta-carotene,” 10 percent or more of the RDI for vitamin A must be present as beta-carotene per reference amount customarily consumed; and

(4) The names of the nutrients that are the subject of the claim are included as part of the claim (e.g., “high in antioxidant vitamins C and E”). Alternatively, when used as part of a nutrient content claim, the term “antioxidant” or “antioxidants” (as in “high in antioxidants”) may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of a product label followed by the name or names of the nutrients with recognized antioxidant activity. The list of nutrients shall appear in letters of a type size height no smaller than the larger of one-half of the type size of the largest nutrient content claim or 1/16 inch. [58 FR 2413, Jan. 6, 1993; 58 FR 17342, Apr. 2, 1993, as amended at 59 FR 394, Jan. 4, 1994; 59 FR 15061, Mar. 31, 1994; 60 FR 17266, Apr. 5, 1995; 61 FR 11731, Mar. 22, 1996; 62 FR 31339, June 9, 1997; 62 FR 49667, 49680, Sept. 23, 1997; 63 FR 26980, May 15, 1998]
§ 101.56 Nutrient content claims for "light" or "lite."

(a) General requirements. A claim using the term light or lite to describe a food may only be made on the label or in labeling of the food if:

(1) The claim uses one of the terms defined 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 is labeled in accordance with § 101.9 or § 101.10, where applicable.

(b) "Light" claims. The terms "light" or "lite" 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), without further qualification, provided that:

(1) If the food derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to an appropriate reference food as specified in § 101.13(j)(1); or
(2) If the food derives less than 50 percent of its calories from fat:
   (i) The number of calories is reduced by at least one-third (33 1/3 percent) per reference amount customarily consumed compared to an appropriate reference food; or
   (ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the reference food that it resembles or for which it substitutes as specified in § 101.13(j)(1); and
(3) As required in § 101.13(j)(2) for relative claims:
   (i) The identity of the reference food and the percent (or fraction) that the sodium was reduced shall be declared in immediate proximity to the most prominent such claim (e.g., 50 percent less sodium than our regular soy sauce); and
   (B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference food that it replaces (e.g., “lite soy sauce 500 milligrams (mg) sodium per serving; regular soy sauce 1,000 mg per serving”) 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.

(c)(1)(i) A product for which the reference food contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the term “light” or “lite” without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference food; and
(2)(i) A product for which the reference food contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the term “light in sodium” or “lite in sodium” if it is reduced by 50 percent or more in sodium content compared to the reference food, provided that “light” or “lite” is presented in immediate proximity with “in sodium” and the entire term is presented in uniform type size, style, color, and prominence; and
(ii) As required in §101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sodium was reduced shall be declared in immediate proximity to the most prominent such claim (e.g., 50 percent less sodium than our regular canned peas); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference food that it replaces (e.g., “lite canned peas, 175 mg sodium per serving; regular canned peas 350 mg per serving”) 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) Except for meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), a “light in sodium” claim may not be made on a food for which the reference food meets the definition of “low in sodium”.

(d)(1) The terms “light” or “lite” may be used on the label or in the labeling of a meal product as defined in §101.13(l) and a main dish product as defined in §101.13(m), provided that:

(i) The food meets the definition of:

(A) “Low in calories” as defined in §101.60(b)(3); or

(B) “Low in fat” as defined in §101.62(b)(3); and

(ii)(A) A statement appears on the principal display panel that explains whether “light” is used to mean “low fat,” “low calories,” or both (e.g., “Light Delight, a low fat, low calories meal”); and

(B) The accompanying statement is no less than one-half the type size of the “light” or “lite” claim.

(2)(i) The term “light in sodium” or “lite in sodium” may be used on the label or in the labeling of a meal product as defined in §101.13(l) and a main dish product as defined in §101.13(m), provided that the food meets the definition of “low in sodium” as defined in §101.61(b)(5); and

(ii) “Light” or “lite” and “in sodium” are presented in uniform type size, style, color, and prominence.

(e) Except as provided in paragraphs (b) through (d) of this section, the term “light” or “lite” may not be used to refer to a food that is not reduced in fat by 50 percent, or, if applicable, in calories by 1/3 or, when properly qualified, in sodium by 50 percent unless:

(1) It describes some physical or organoleptic attribute of the food such as texture or color and the information (e.g., “light in color” or “light in texture”) so stated, clearly conveys the nature of the product; and

(2) The attribute (e.g., “color” or “texture”) is in the same style, color, and at least one-half the type size as the word “light” and in immediate proximity thereto.

(f) If a manufacturer can demonstrate that the word “light” has been associated, through common use, with a particular food to reflect a physical or organoleptic attribute (e.g., light brown sugar, light corn syrup, or light molasses) to the point where it has become part of the statement of identity, such use of the term “light” shall not be considered a nutrient content claim subject to the requirements in this part.

(g) The term “lightly salted” may be used on a product to which has been added 50 percent less sodium than is normally added to the reference food as described in §101.13(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not “low in sodium” as defined in §101.61(b)(4), the statement “not a low sodium food” shall appear adjacent to the nutrition label of the food bearing the claim, or, if the nutrition label is on the information panel, it may appear elsewhere on the information panel in accordance with §101.2 and the information required to accompany a relative claim shall appear on the label or labeling as specified in §101.13(j)(2).
(1) The claim uses one of the terms defined 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;
(3) The food for which the claim is made is labeled in accordance with §101.9, §101.10, or §101.36, as applicable; and
(4) For dietary supplements, claims regarding calories may not be made on products that meet the criteria in §101.60(b)(1) or (b)(2) for "calorie free" or "low calorie" claims except when an equivalent amount of a similar dietary supplement that the labeled food resembles and for which it substitutes, normally exceeds the definition for "low calorie" in §101.60(b)(2).

(b) Calorie content claims.

(1) The terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietarily insignificant source of calories" may be used on the label or in labeling of foods, provided that:
   (i) The food contains less than 5 calories per reference amount customarily consumed and per labeled serving;
   (ii) As required in §101.13(e)(2), if the food meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to disclose that calories are not usually present in the food (e.g., "cider vinegar, a calorie free food").

(2) The terms "low calorie," "few calories," "contains a small amount of calories," "low source of calories," or "low in calories" 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:
   (i) The product contains 120 calories or less per 100 g; and
   (ii) If the product contains 120 calories or less per 100 g, the food contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference food as described in §101.13(j)(1); and
   (iii) As required in §101.13(j)(2) for relative claims:
      (A) The identity of the reference food and the percent (or fraction) that the calories differ between the two foods are declared in immediate proximity to the most prominent such claim (e.g., reduced calorie cupcakes "33 1/3 percent fewer calories than regular cupcakes"); and
§ 101.60

(B) Quantitative information comparing the level of the nutrient per labeled serving size with that of the reference food that it replaces (e.g., “Calorie content has been reduced from 150 to 100 calories per serving.”) 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 (b)(4) of this section may not be made on the label or labeling of foods if the reference food meets the definition for “low calorie.”

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent fewer calories per 100 g of food than an appropriate reference food as described in § 101.13(j); and

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

(A) The identity of the reference food and the percent (or fraction) that the calories differ between the two foods are declared in immediate proximity to the most prominent such claim (e.g., Larry’s Reduced Calorie Lasagna, “25 percent fewer calories per oz. (or 3 oz) than our regular Lasagna”); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., “Calorie content has been reduced from 108 calories per 3 oz to 83 calories per 3 oz.”) 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 (b)(5) of this section may not be made on the label or labeling of food if the reference food meets the definition for “low calorie.”

(c) Sugar content claims—(1) Use of terms such as “sugar free,” “free of sugar,” “no sugar,” “zero sugar,” “without sugar,” “sugarless,” “trivial source of sugar,” “negligible source of sugar,” or “dietarily insignificant source of sugar.”

Consumers may reasonably be expected to regard terms that represent that the food contains no sugars or sweeteners e.g., “sugar free,” or “no sugar,” as indicating a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a food may not be labeled with such terms unless:

(i) The food contains less than 0.5 g of sugars, as defined in § 101.9(c)(6)(ii), per reference amount customarily consumed and per labeled serving or, in the case of a meal product or main dish product, less than 0.5 g of sugars per labeled serving; and

(ii) The food contains no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states “adds a trivial amount of sugar,” “adds a negligible amount of sugar,” or “adds a dietarily insignificant amount of sugar;” and

(iii)(A) It is labeled “low calorie” or “reduced calorie” or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, or, if a dietary supplement, it meets the definition in paragraph (b)(2) of this section for “low calorie” but is prohibited by §§ 101.13(b)(5) and 101.60(a)(4) from bearing the claim; or

(B) Such term is immediately accompanied, each time it is used, by either the statement “not a reduced calorie food,” “not a low calorie food,” or “not for weight control.”

(2) The terms “no added sugar,” “without added sugar,” or “no sugar added” may be used only if:

(i) No amount of sugars, as defined in § 101.9(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging; and

(ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice; and
(iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a food, and a functionally insignificant increase in sugars results; and
(iv) The food that it resembles and for which it substitutes normally contains added sugars; and
(v) The product bears a statement that the food is not "low calorie" or "calorie reduced" (unless the food meets the requirements for a "low" or "reduced calorie" food) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content.
(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a food, including foods intended specifically for infants and children less than 2 years of age, is unsweetened or contains no added sweeteners in the case of a food that contains apparent substantial inherent sugar content, e.g., juices.
(4) The claims provided for in paragraph (c)(1) and (c)(2) of this section may be used on labels or in labeling of dietary supplements of vitamins or minerals that are intended specifically for use by infants and children less than 2 years of age.
(5) The terms "reduced sugar," "reduced in sugar," "sugar reduced," "less sugar," "lower sugar" or "lower in sugar" may be used on the label or in labeling of foods, except meal products as defined in §101.13(l), main dish products as defined in §101.13(m), and dietary supplements of vitamins or minerals, provided that:
(i) The food contains at least 25 percent less sugars per 100 g of food than an appropriate reference food as described in §101.13(j)(1), and
(ii) As required in §101.13(j)(2) for relative claims:
(A) The identity of the reference food and the percent (or fraction) that the sugars differ between the two foods are declared in immediate proximity to the most prominent such claim (e.g., reduced sweet and sour shrimp dinner, "25 percent less sugar per 3 oz than our regular sweet and sour shrimp dinner"); and
(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., "Sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz.") 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.
(6) The terms defined in paragraph (c)(5) of this section may be used on the label or in the labeling of a meal product as defined in §101.13(l) and a main dish product as defined in §101.13(m), provided that:
(i) The food contains at least 25 percent less sugars per 100 g of food than an appropriate reference food as described in §101.13(j)(1), and
(ii) As required in §101.13(j)(2) for relative claims:
(A) The identity of the reference food and the percent (or fraction) that the sugars differ between the two foods are declared in immediate proximity to the most prominent such claim (e.g., reduced sweet and sour shrimp dinner, "25 percent less sugar per 3 oz than our regular sweet and sour shrimp dinner"); and
(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., "Sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz.") 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.
§ 101.61  21 CFR Ch. I (4-1-99 Edition)

(1) The claim uses one of the terms defined 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) Sodium content claims. (1) The terms “sodium free,” “free of sodium,” “no sodium,” “zero sodium,” “without sodium,” “trivial source of sodium,” “negligible source of sodium,” or “dietary insignificant source of sodium” may be used on the label or in the labeling of foods, provided that:

(i) The food contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per labeled serving or, in the case of a meal product or a main dish product, less than 5 mg of sodium per labeled serving; and

(ii) The food contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium, unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: “Adds a trivial amount of sodium,” “adds a negligible amount of sodium,” or “adds a dietarily insignificant amount of sodium;” and

(iii) As required in §101.13(e)(2) if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to disclose that sodium is not usually present in the food (e.g., “leaf lettuce, a sodium free food”).

(2) The terms “very low sodium,” or “very low in sodium,” 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:

(i)(A) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contains 140 mg or less sodium per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 35 mg or less sodium per reference amount customarily consumed and 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)(3), of all nutrients per reference amount customarily consumed, the per 50-g criterion refers to the “as prepared” form);

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., “potatoes, a very low-sodium food”).

(3) The terms defined in paragraph (b)(2) 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:

(i) The product contains 35 mg or less of sodium per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms “low sodium,” or “low in sodium,” “little sodium,” “contains a small amount of sodium,” or “low source of sodium” 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:

(i)(A) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contains 140 mg or less sodium per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 35 mg or less sodium per reference amount customarily consumed,
the per 50-g criterion refers to the “as prepared” form); and
(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., “fresh spinach, a low sodium food”); and

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of meats, products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:
(i) The product contains 140 mg or less sodium per 100 g; and
(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(6) The terms “reduced sodium,” “reduced in sodium,” “sodium reduced,” “less sodium,” “lower sodium,” or “lower in sodium” 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:
(i) The food contains at least 25 percent less sodium per 100 g of food than an appropriate reference food as described in §101.13(j)(1), and
(ii) As required in §101.13(j)(2) for relative claims:
(A) The identity of the reference food and the percent (or fraction) that the sodium differs from the reference food are declared in immediate proximity to the most prominent such claim (e.g., “reduced sodium eggplant parmigiana dinner, 30 percent less sodium per oz (or 3 oz) than our regular eggplant parmigiana dinner”).

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference food that it replaces (e.g., “Sodium content has been reduced from 217 mg per 3 oz to 150 mg per 3 oz.”) 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 (b)(6) 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 sodium.”

(7) The terms defined in paragraph (b)(6) of this section may be used on the label or in the labeling of meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:
(i) The food contains at least 25 percent less sodium per 100 g of food than an appropriate reference food as described in §101.13(j)(1), and
(ii) As required in §101.13(j)(2) for relative claims:
(A) The identity of the reference food and the percent (or fraction) that the sodium differs from the reference food are declared in immediate proximity to the most prominent such claim (e.g., reduced sodium eggplant parmigiana dinner “30 percent less sodium per oz (or 3 oz) than our regular eggplant parmigiana dinner”).

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference food that it replaces (e.g., “Sodium content has been reduced from 217 mg per 3 oz to 150 mg per 3 oz.”) 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 (b)(7) 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 sodium.”

(c) The term “salt” is not synonymous with “sodium.” Salt refers to sodium chloride. However, references to salt content such as “unsalted,” “no salt,” “no salt added” are potentially misleading.

(1) The term “salt free” may be used on the label or in labeling of foods only if the food is “sodium free” as defined in paragraph (b)(1) of this section.
§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

(a) General requirements. A claim about the level of fat, fatty acid, and cholesterol in a food may only be made on the label or in labeling of foods if:

(1) The claim uses one of the terms defined 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;

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

(4) For dietary supplements, claims for fat, saturated fat, and cholesterol may not be made on products that meet the criteria in §101.60(b)(1) or (b)(2) for “calorie free” or “low calorie” claims.

(b) Fat content claims. (1) The terms “fat free,” “free of fat,” “no fat,” “zero fat,” “without fat,” “negligible source of fat,” or “dietarily insignificant source of fat” or, in the case of milk products, “skim” may be used on the label or in labeling of foods, provided that:

(i) The food contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving or, in the case of a meal product or main dish product, less than 0.5 g of fat per labeled serving; and

(ii) The food contains no added ingredient that is a fat or is generally understood by consumers to contain fat unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states “adds a trivial amount of fat,” “adds a negligible amount of fat,” or “adds a dietarily insignificant amount of fat;” and

(iii) As required in §101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to disclose that fat is not usually present in the food (e.g., “broccoli, a fat free food”).

(2) The terms “low fat,” “low in fat,” “contains a small amount of fat,” “low source of fat,” or “little fat” 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:

(i)(A) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contains 3 g or less of fat per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g of food (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); and

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all foods of

(3) Paragraph (c)(2) of this section shall not apply to a factual statement that a food intended specifically for infants and children less than 2 years of age is unsalted, provided such statement refers to the taste of the food and is not otherwise false and misleading.

its type and not merely to the particular brand to which the label attaches (e.g., “frozen perch, a low fat food”).

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of meal products as defined in §101.13(l) or main dish products as defined in §101.13(m), provided that:

(i) The product contains 3 g or less of total fat per 100 g and not more than 30 percent of calories from fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms “reduced fat,” “reduced in fat,” “fat reduced,” “less fat,” “lower fat,” or “lower in fat” 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:

(i) The food contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference food as described in §101.13(j)(1); and

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

(A) The identity of the reference food and the percent (or fraction) that the fat differs between the two foods and are declared in immediate proximity to the most prominent such claim (e.g., “reduced fat spinach souffle, “33 percent less fat per 3 oz than our regular spinach souffle”); and

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference food that it replaces (e.g., “Fat content has been reduced from 7.5 g per 3 oz to 5 g per 3 oz.”) is declared adjacent to the most prominent claim, to the nutrition label, or, if the nutrition label is located on the information panel, it may appear elsewhere on the information panel in accordance with §101.2.

(iii) Claims described in paragraph (b)(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 fat.”

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in the labeling of meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:

(i) The food contains at least 25 percent less fat per 100 g of food than an appropriate reference food as described in §101.13(j)(1); and

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

(A) The identity of the reference food and the percent (or fraction) that the fat differs between the two foods are declared in immediate proximity to the most prominent such claim (e.g., reduced fat spinach souffle, “33 percent less fat per 3 oz than our regular spinach souffle”); and

(B) Quantitative information comparing the level of fat in the product per labeled serving with that of the reference food that it replaces (e.g., “Fat content has been reduced from 8 g to 4 g per serving.”) is declared adjacent to the most prominent claim, to the nutrition label, or, if the nutrition label is on the information panel, it may appear elsewhere on the information panel in accordance with §101.2.

(iii) Claims described in paragraph (b)(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 fat.”

(6) The term “low fat” may be used on the label or in labeling of foods, provided that:

(i) The food contains 3 g or less of total fat per 100 g and not more than 30 percent of calories from fat; and

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(iii) Claims described in paragraph (b)(4) 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 fat.”

§ 101.62

Fatty acid content claims. The label or labeling of foods that bear claims with respect to the level of saturated fat shall disclose the level of total fat and cholesterol in the food in immediate proximity to such claim each time the claim is made and in type.
that shall be no less than one-half the size of the type used for the claim with respect to the level of saturated fat. Declaration of cholesterol content may be omitted when the food contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed or in the case of a meal or main dish product less than 2 mg of cholesterol per labeled serving. Declaration of total fat may be omitted with the term defined in paragraph (c)(1) of this section when the food contains less than 0.5 g of total fat per reference amount customarily consumed or, in the case of a meal product or a main dish product, when the product contains less than 0.5 g of total fat per labeled serving. The declaration of total fat may be omitted with the terms defined in paragraphs (c)(2) through (c)(5) of this section when the food contains 3 g or less of total fat per reference amount customarily consumed or in the case of a meal product or a main dish product, when the product contains 3 g or less of total fat per 100 g and not more than 30 percent calories from fat.

(1) The terms “saturated fat free,” “free of saturated fat,” “no saturated fat,” “zero saturated fat,” “without saturated fat,” “trivial source of saturated fat,” “negligible source of saturated fat,” or “dietarily insignificant source of saturated fat” may be used on the label or in the labeling of foods, provided that:

(i) The food contains less than 0.5 g of saturated fatty acids per reference amount customarily consumed and per labeled serving, or in the case of a meal product or main dish product, less than 0.5 g of saturated fat and less than 0.5 g trans fatty acid per labeled serving; and

(ii) The food contains no ingredient that is generally understood by consumers to contain saturated fat unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients which states, “adds a trivial amount of saturated fat,” “adds a negligible amount of saturated fat,” or “adds a dietarily insignificant amount of saturated fat;” and

(iii) As required in §101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to disclose that saturated fat is not usually present in the food.

(2) The terms “low in saturated fat,” “low saturated fat,” “contains a small amount of saturated fat,” “low source of saturated fat,” or “a little saturated fat” 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:

(i) The food contains 1 g or less of saturated fatty acids per reference amount customarily consumed and not more than 15 percent of calories from saturated fatty acids; and

(ii) If a food meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., “raspberries, a low saturated fat food”).

(3) The terms defined in paragraph (c)(2) of this section may be used on the label or in the labeling of meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:

(i) The product contains 1 g or less of saturated fatty acids per 100 g and not more than 10 percent calories from saturated fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms “reduced saturated fat,” “reduced in saturated fat,” “saturated fat reduced,” “less saturated fat,” “lower saturated fat,” or “lower in saturated fat” may be used on the label or in the labeling of foods, except as limited by §101.13(j)(1)(i) and except meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:
Food and Drug Administration, HHS § 101.62

(i) The food contains at least 25 percent less saturated fat per reference amount customarily consumed than an appropriate reference food as described in §101.13(j)(1); and

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

(A) The identity of the reference food and the percent (or fraction) that the saturated fat differs between the two foods are declared in immediate proximity to the most prominent such claim (e.g., “reduced saturated fat. Contains 50 percent less saturated fat than the national average for nondairy creamers”); and

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving with that of the reference food that it replaces (e.g., “Saturated fat reduced from 3 g to 1.5 g per serving”) 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 (c)(4) 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 saturated fat.”

(d) Cholesterol content claims. (1) The terms “cholesterol free,” “free of cholesterol,” “zero cholesterol,” “without cholesterol,” “no cholesterol,” “trivial source of cholesterol,” “negligible source of cholesterol,” or “dietarily insignificant source of cholesterol” may be used on the label or in the labeling of foods, provided that:

(i) For foods that contain 13 g or less of total fat per reference amount customarily consumed, per labeled serving, and per 50 g if the reference amount customarily consumed is 30 g or less or 2 tablespoons or less (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, per labeled serving), or, in the case of main dish products, 26.0 g or less total fat per labeled serving:

(A) The food contains less than 2 mg of cholesterol per reference amount customarily consumed, and

(B) The food contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states “adds a trivial amount of cholesterol,” “adds a negligible amount of...”
cholesterol;'' or "adds a dietarily insignificant amount of cholesterol;'' and

(C) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed or, in the case of a meal product or main dish product, 2 g or less of saturated fatty acids per labeled serving; and

(D) As required in §101.13(e)(2), if the food contains less than 2 mg of cholesterol per reference amount customarily consumed or in the case of a meal product or main dish product, less than 2 mg of cholesterol per labeled serving without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the food (e.g., "applesauce, a cholesterol-free food").

(ii) For food that contain more than 13 g of total fat per reference amount customarily consumed, per labeling serving, or per 50 g if the reference amount customarily consumed is 30 g or less or 2 tablespoons or less (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), or in the case of a meal product, more than 26 g of total fat per labeled serving, or, in the case of a main dish product more than 19.5 g of total fat per labeled serving:

(A) The food contains less than 2 mg of cholesterol per reference amount customarily consumed and per labeling serving or, in the case of a meal product or main dish product, less than 2 mg of cholesterol per labeled serving; and

(B) The food contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states "adds a trivial amount of cholesterol," "adds a negligible amount of cholesterol," or "adds a dietarily insignificant amount of cholesterol;" and

(C) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed or, in the case of a meal product or main dish product less than 2 g of saturated fatty acids per labeled serving; and

(D) 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 appears 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

(E) As required in §101.13(e)(2), if the food contains less than 2 mg of cholesterol per reference amount customarily consumed or in the case of a meal product or main dish product less than 2 mg of cholesterol per labeled serving without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the food (e.g., "canola oil, a cholesterol-free food, contains 14 g of fat per serving"); or

(F) If the food contains less than 2 mg of cholesterol per reference amount customarily consumed or in the case of a meal product or main dish product less than 2 mg of cholesterol per labeled serving only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(4)(ii)(A) of this section) than the food 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. 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 was reduced or that 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. 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 was reduced are declared in immediate proximity to the most prominent such claim (e.g., "cholesterol-free margarine, contains 100 percent less cholesterol than butter"); and

(2) Quantitative information comparing the level of cholesterol in the product per labeled serving with that...
of the reference food that it replaces (e.g., “Contains no cholesterol compared with 30 mg cholesterol in one serving of butter. Contains 13 g of fat per serving.”) 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.

(2) The terms “low in cholesterol,” “low cholesterol,” “contains a small amount of cholesterol,” “low source of cholesterol,” or “little cholesterol” 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:

(i) For foods that have a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contain 13 g or less of total fat per reference amount customarily consumed and per labeled serving:

(A) The food contains 20 mg or less of cholesterol per reference amount customarily consumed;

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed; and

(C) As required in §101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., “low fat cottage cheese, a low cholesterol food”).

(ii) For foods that have a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contain more than 13 g of total fat per reference amount customarily consumed or per labeled serving,

(A) The food contains 20 mg or less of cholesterol per reference amount customarily consumed;

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed; and

(C) As required in §101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., “low fat cottage cheese, a low cholesterol food”).

(iii) For foods that have a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contain more than 13 g of total fat per reference amount customarily consumed or per labeled serving,

(A) The food contains 20 mg or less of cholesterol per reference amount customarily consumed;

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed;

(C) As required in §101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., “low fat cottage cheese, a low cholesterol food”).

(D) As required in §101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches; or
(E) If the food contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(4)(ii)(A) of this section) than the food 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. 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., “low-cholesterol peanut butter sandwich crackers, contains 83 percent less cholesterol than our regular peanut butter sandwich crackers”); and

2. Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces (e.g., “Cholesterol lowered from 30 mg to 5 mg per serving; contains 13 g of fat per serving.”) 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.

(iv) For foods that have a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contain more than 13 g of total fat per reference amount customarily consumed, per labeled serving, or 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).

(A) The food contains 20 mg or less of cholesterol per reference amount customarily consumed and 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).

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed;

(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(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches; or

(E) If the food contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(4)(ii)(A) of this section) than the food for which it substitutes as specified in §101.13(d) that has a significant (i.e., 5 percent or more of a national or regional market) market share. 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., “low-cholesterol peanut butter sandwich crackers, contains 83 percent less cholesterol than our regular peanut butter sandwich crackers”); and

2. Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces (e.g., “Cholesterol lowered from 30 mg to 5 mg per serving; contains 13 g of fat per serving.”) 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.  

(3) The terms defined in paragraph (d)(2) of this section may be used on the label and in labeling of meal products as defined in §101.13(l) or a main dish product as defined in §101.13(m) provided that the product meets the requirements of paragraph (d)(2) of this section except that the determination as to whether paragraph (d)(2)(i) or (d)(2)(iii) of this section applies to the product will be made only on the basis of whether the meal product contains 26 g or less of total fat per labeled serving or the main dish product contain 19.5 g or less of total fat per labeled serving, the requirement in paragraphs (d)(2)(i)(A) and (d)(2)(iii)(A) of this section shall be limited to 20 mg of cholesterol per 100 g, and the requirement in paragraphs (d)(2)(i)(B) and (d)(2)(iii)(B) of this section shall be modified to require that the food contain 2 g or less of saturated fat per 100 g rather than per reference amount customarily consumed.  

(4) The terms “reduced cholesterol,” “reduced in cholesterol,” “cholesterol reduced,” “less cholesterol,” “lower cholesterol,” or “lower in cholesterol” except as limited by §101.13(j)(1) may be used on the label or in labeling of foods or foods that substitute for those foods as specified in §101.13(d), excluding meal products as defined in §101.13(l) and main dish products as defined in §101.13(m), provided that:

(i) For foods that contain 13 g or less of total fat per reference amount customarily consumed, per labeled serving, and per 50 g if the reference amount customarily consumed is 30 g or less or 2 tablespoons or less (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):

(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 (i.e., 5 percent or more) market share; and  

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed; and  

(C) 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; and  

(2) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces (e.g., “[labeled product] 50 mg cholesterol per serving; [reference product] 30 mg cholesterol per serving”) 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.  

(ii) For foods that contain more than 13 g of total fat per reference amount customarily consumed, per labeled serving, or per 50 g if the reference amount customarily consumed is 30 g or less or 2 tablespoons or less (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):

(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 (i.e., 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 reference amount customarily consumed;  

(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% less cholesterol per 3 oz 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 content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz.”) 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.

(ii) For meal products that contain more than 26.0 g of total fat per labeled serving or for main dish products that 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; and

(C) 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% less cholesterol per 3 oz 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 content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz.”) 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)(4) of this section may not be made 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:

(i) For meal products that contain 26.0 g or less of total fat per labeled serving or for main dish products that contain 19.5 g or less 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

110
Food and Drug Administration, HHS

§ 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) 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, before 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.

(d) Paragraphs (d)(1) through (d)(6) of this section are 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 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)(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) 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 following 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.


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 (4)(ii)(B) were stayed until Jan. 1, 2000. At 64 FR 12887, Mar. 16, 1999, paragraphs (d) (2)(ii)(C), (3)(ii)(C), and (4)(ii)(B) were stayed until Jan. 1, 2003.

§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 sweetness. The product may contain water to replace milkfat although the amount of water in the product shall be less than the amount of cream, milk, or milk constituents;

(3) The product is not nutritionally inferior, as defined in §101.3(e)(4), to butter as produced under 21 U.S.C. 321a;

(4) If the product would violate 21 U.S.C. 321a but for the nutrient content claim that characterizes the level of nutrients, that claim shall be an explicit claim that is included as part of the common or usual name of the product.

(b) Deviations from the ingredient provisions of 21 U.S.C. 321a must be the minimum necessary to achieve similar performance characteristics as butter as produced under 21 U.S.C. 321a, and

(1) 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 water to replace milkfat although the amount of water in the product shall be less than the amount of cream, milk, or milk constituents;
the product shall be similar to butter as produced under 21 U.S.C. 321a. If there is a significant difference in performance characteristics (that materially limits the uses of the product compared to butter,) the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for baking purposes"). Such statement shall comply with the requirements of §101.13(d). The modified product shall perform at least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a.

(c)(1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of this part.

(2) Safe and suitable ingredients added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness and water added to replace milkfat shall be identified with an asterisk in the ingredient statement. The statement "*Ingredients not in regular butter" shall immediately follow the ingredient statement in the same type size.

[58 FR 2455, Jan. 6, 1993]

§ 101.69 Petitions for nutrient content claims.

(a) This section pertains to petitions for claims, expressed or implied, that:

(1) Characterize the level of any nutrient which is of the type required to be in the label or labeling of food by section 403(q)(1) or (q)(2) of the Federal Food, Drug, and Cosmetic Act (the act); and

(2) That are not exempted under section 403(r)(5)(A) through (r)(5)(C) of the act from the requirements for such claims in section 403(r)(2).

(b) Petitions included in this section are:

(1) Petitions for a new (heretofore unauthorized) nutrient content claim;

(2) Petitions for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient; and

(3) Petitions for the use of an implied claim in a brand name.

(c) An original and one copy of the petition to be filed under the provisions of section 403(r)(4) of the act shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. Petitioners interested in submitting a disk should contact the Food and Drug Administration’s (FDA) Center for Food Safety and Applied Nutrition for details. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner’s post office address to which published notices as required by section 403 of the act may be sent.

(d) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of FDA. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies are included in a petition submitted under section 403(r)(4) of the act, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations are included in a petition submitted under section 403(r)(4) of the act, the petition shall include a statement regarding each such clinical investigation relied upon in the petition that the study either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with §56.104 or §56.105 of this chapter, and that it was...
§ 101.69

conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(g) The availability for public disclosure of petitions submitted to the agency under this section will be governed by the rules specified in §10.20(j) of this chapter.

(h) All petitions submitted under this section shall include either a claim for a categorical exclusion under §25.30 or 25.32 of this chapter or an environmental assessment under §25.40 of this chapter.

(i) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application from the petitioner, the present petition may incorporate it by specific reference to the earlier petition.

(j) The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(k) The petition shall include a statement signed by the person responsible for the petition, that to the best of his knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him pertinent to the evaluation of the petition.

(l) All applicable provisions of part 10—Administrative Practices and Procedures, may be used by FDA, the petitioner or any outside party with respect to any agency action on the petition.

(m)(1) Petitions for a new nutrient content claim shall include the following data and be submitted in the following form.

(Date)
Name of petitioner
Post office address
Subject of the petition
Office of Food Labeling (HF S-150)
Food and Drug Administration,
Department of Health and Human Services,
Washington, DC 20204.
To Whom It May Concern:

The undersigned, — submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the claim and its proposed use).

Attached hereto and constituting a part of this petition, are the following:

A. A statement identifying the descriptive term and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement should address why the use of the term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of foods on which the claim will be used. The statement shall specify the level at which the nutrient must be present or what other conditions concerning the food must be met for the use of the term in labels or labeling to be appropriate, as well as any factors that would make the use of the term inappropriate.

B. A detailed explanation, supported by any necessary data, of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation under section 403(r)(2)(A)(i) of the act. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose.

C. Analytical data that shows the amount of the nutrient that is the subject of the claim and that is present in the types of foods for which the claim is intended. The assays should be performed on representative samples using the Association of Official Analytical Chemists International (AOAC International) methods where available. If no AOAC International method is available, the petitioner shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data should include a statistical analysis of the analytical and product variability.

D. A detailed analysis of the potential effect of the use of the proposed claim on food consumption and of foods containing changes in nutrient intake. The latter item shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such group and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

E. The petitioner is required to submit either a claim for categorical exclusion under §25.30 or §25.32 of this chapter or an environmental assessment under §25.40 of this chapter.

Yours very truly,
Food and Drug Administration, HHS

§ 101.69

Petitioner

By ____________________________

(Indicate authority)

(2) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received by the agency. Such notice will inform the petitioner:

(i) That the petition is undergoing agency review (in which case a docket number will be assigned to the petition), and the petitioner will subsequently be notified of the agency’s decision to file or deny the petition; or

(ii) That the petition is incomplete, e.g., it lacks any of the data required by this part, it presents such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 100 days of the date of receipt of the petition, FDA will notify the petitioner by letter that the petition has either been filed or denied. If denied, the notification shall state the reasons therefor. If filed, the date of the notification letter becomes the date of filing for the purposes of section 403(r)(4)(A)(i) of the act. If FDA does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the FDA and the petitioner.

(4) Within 90 days of the date of filing FDA will by letter of notification to the petitioner:

(i) Deny the petition; or

(ii) Inform the petitioner that a proposed regulation to provide for the requested use of the new term will be published in the FEDERAL REGISTER. FDA will publish the proposal to amend the regulations to provide for the requested use of the nutrient content claim in the FEDERAL REGISTER within 90 days of the date of filing. The proposal will also announce the availability of the petition for public disclosure.

(iii) If FDA does not act within 90 days of the date of filing, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

(5) If FDA issues a proposal, the rule-making shall be completed within 540 days of the date of receipt of the petition.

(n)(1) Petitions for a synonymous term shall include the following data and be submitted in the following form.

To Whom It May Concern:

The undersigned, ____________________________ submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to a statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under section 403(r)(2) of the act.

Attached hereto and constituting a part of this petition, are the following:

A. A statement identifying the synonymous descriptive term, the existing term defined by a regulation under section 403(r)(2)(A)(i) of the act with which the synonymous term is claimed to be consistent. The statement should address why the proposed synonymous term is consistent with the term already defined by the agency, and why the use of the synonymous term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of foods on which the claim will be used. The statement shall specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

B. A detailed explanation, supported by any necessary data, of why use of the proposed term is requested, including an explanation of whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This item shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing term defined by regulation. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose.
§ 101.69

C. The petitioner is required to submit either a claim for categorical exclusion under §25.30 or §25.32 of this chapter or an environmental assessment under §25.40 of this chapter.

Yours very truly,
Petitioner
By

(Indicate authority)

(2) Within 15 days of receipt of the petition the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner:

(i) That the petition is undergoing agency review (in which case a docket number will be assigned to the petition) and the petitioner will subsequently be notified of the agency's decision to grant the petitioner permission to use the proposed term or to deny the petition; or

(ii) That the petition is incomplete, e.g., it lacks any of the data required by this part, it presents such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 90 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and consequently denied, FDA will notify the petitioner by letter of the agency's decision to grant the petitioner permission to use the proposed term, with any conditions or limitations on such use specified, or to deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition to fully address the requirements of this section shall be grounds for denial of the petition.

(4) As soon as practicable following the agency's decision to either grant or deny the petition, FDA will publish a notice in the Federal Register informing the public of his decision. If the petition is granted the Food and Drug Administration will list, the approved synonymous term in the regulations listing terms permitted for use in nutrient content claims.

(o)(1) Petitions for the use of an implied nutrient content claim in a brand name shall include the following data and be submitted in the following form:

(2) Within 15 days of receipt of the petition the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner:
Subpart E—Specific Requirements for Health Claims

§ 101.70 Petitions for health claims.

(a) Any interested person may petition the Food and Drug Administration (FDA) to issue a regulation regarding a health claim. An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.) If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which any correspondence required by section 403 of the Federal Food, Drug, and Cosmetic Act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of FDA. Such information may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area. Any reference to published information shall be accompanied by reprints, or easily readable copies of such information.

(c) If nonclinical laboratory studies are included in a petition, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d) If clinical or other human investigations are included in a petition, the petition shall include a statement that they were either conducted in compliance with the requirements for institutional review set forth in part 56 of this