that is enclosed in an outer package to comply with these type size requirements, the type size of the nutrition label on the primary (inner) container may be as small as needed to accommodate all of the required label information provided that the primary container is securely enclosed in outer packaging, the nutrition labeling on the outer packaging meets the applicable type size requirements, and such outer packaging is not intended to be separated from the primary container under conditions of retail sale.

(v) Where there is not sufficient space on a small or intermediate-sized package for a nutrition label that meets minimum type size requirements of 4.5 points if hairlines are used in accordance with paragraph (e)(5) of this section, the hairlines may be omitted and replaced by a row of dots connecting the columns containing the name of each dietary ingredient and the quantitative amounts (by weight and as a percent of Daily Value).

(3) Section 101.9(j)(15) for foods in multiunit food containers;

(4) Section 101.9(j)(16) for foods sold in bulk containers; and

(5) Section 101.9(j)(17) for foods in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required label information, except that the ingredient list shall continue to be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label as specified in § 101.4(g).

(j) Dietary supplements shall be subject to the misbranding provisions of § 101.9(k).

[62 FR 49849, Sept. 23, 1997, as amended at 63 FR 30620, June 5, 1998; 66 FR 56035, Nov. 6, 2001; 71 FR 51726, Aug. 31, 2006; 71 FR 74791, Dec. 13, 2006; 81 FR 33994, May 27, 2016; 83 FR 65502, Dec. 21, 2018]

§ 101.42 Nutrition labeling of raw fruit, vegetables, and fish.

(a) The Food and Drug Administration (FDA) urges food retailers to provide nutrition information, as provided in § 101.9(c), for raw fruit, vegetables, and fish at the point-of-purchase. If retailers choose to provide such information, they should do so in a manner that conforms to the guidelines in § 101.45.

(b) In § 101.44, FDA has listed the 20 varieties of raw fruit, vegetables, and fish that are most frequently consumed during a year and to which the guidelines apply.

(c) FDA has also defined in § 101.43, the circumstances that constitute substantial compliance by food retailers with the guidelines.

(d) By May 8, 1993, FDA will issue a report on actions taken by food retailers to provide consumers with nutrition information for raw fruit, vegetables, and fish under the guidelines established in § 101.45.

(1) The report will include a determination of whether there is substantial compliance, as defined in § 101.43, with the guidelines.

(2) In evaluating substantial compliance, FDA will consider only the 20 varieties of raw fruit, vegetables, and fish most frequently consumed as identified in § 101.44.

(e) If FDA finds that there is substantial compliance with the guidelines for the nutrition labeling of raw fruit and vegetables or of fish, the agency will so state in the report, and the guidelines will remain in effect. FDA will reevaluate the market place for substantial compliance every 2 years.

(f) If FDA determines that there is not substantial compliance with the guidelines for raw fruit and vegetables or for raw fish, the agency will at that time issue proposed regulations requiring that any person who offers raw fruit and vegetables or fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by § 101.9. Final regulations would have to be issued 6 months after issuance of proposed regulations, and they would become effective 6 months after the date of their promulgation.

§ 101.43 Substantial compliance of food retailers with the guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.

(a) The Food and Drug Administration (FDA) will judge a food retailer

who sells raw agricultural commodities or raw fish to be in compliance with the guidelines in § 101.45 with respect to raw agricultural commodities if the retailer displays or provides nutrition labeling for at least 90 percent of the raw agricultural commodities listed in § 101.44 that it sells, and with respect to raw fish if the retailer displays or provides nutrition labeling for at least 90 percent of the types of raw fish listed in § 101.44 that it sells. To be in compliance, the nutrition labeling shall:

(1) Be presented in the store or other type of establishment in a manner that is consistent with § 101.45(a)(1);

(2) Be presented in content and format that are consistent with § 101.45 (a)(2), (a)(3), and (a)(4); and

(3) Include data that have been provided by FDA in appendices C and D to part 101 of this chapter, except that the information on potassium is voluntary.

(b) To determine whether there is substantial compliance by food retailers with the guidelines in § 101.45 for the voluntary nutrition labeling of raw fruit and vegetables and of raw fish, FDA will select a representative sample of 2,000 stores, allocated by store type and size, for raw fruit and vegetables and for raw fish.

(c) FDA will find that there is substantial compliance with the guidelines in § 101.45 if it finds based on paragraph (a) of this section that at least 60 percent of all stores that are evaluated are in compliance.

(d) FDA will evaluate substantial compliance separately for raw agricultural commodities and for raw fish.

[55 FR 60890, Nov. 27, 1991, as amended at 61 FR 42759, Aug. 16, 1996]

§ 101.44 What are the 20 most frequently consumed raw fruits, vegetables, and fish in the United States?

(a) The 20 most frequently consumed raw fruits are: Apple, avocado (California), banana, cantaloupe, grapefruit, grapes, honeydew melon, kiwifruit, lemon, lime, nectarine, orange, peach, pear, pineapple, plums, strawberries, sweet cherries, tangerine, and watermelon.

(b) The 20 most frequently consumed raw vegetables are: Asparagus, bell pepper, broccoli, carrot, cauliflower, celery, cucumber, green (snap) beans, green cabbage, green onion, iceberg lettuce, leaf lettuce, mushrooms, onion, potato, radishes, summer squash, sweet corn, sweet potato, and tomato.

(c) The 20 most frequently consumed raw fish are: Blue crab, catfish, clams, cod, flounder/sole, haddock, halibut, lobster, ocean perch, orange roughy, oysters, pollock, rainbow trout, rockfish, salmon (Atlantic/coho/Chinook/sockeye, chum/pink), scallops, shrimp, swordfish, tilapia, and tuna.

[71 FR 42044, July 25, 2006]

§ 101.45 Guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish.

(a) Nutrition labeling for raw fruits, vegetables, and fish listed in § 101.44 should be presented to the public in the following manner:

(1) Nutrition labeling information should be displayed at the point of purchase by an appropriate means such as by a label affixed to the food or through labeling including shelf labels, signs, posters, brochures, notebooks, or leaflets that are readily available and in close proximity to the foods. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

(2) Serving sizes should be determined, and nutrients declared, in accordance with § 101.9 (b) and (c), respectively, except that the nutrition labeling data should be based on the raw edible portion for fruits and vegetables and on the cooked edible portion for fish. The methods used to cook fish should be those that do not add fat, breading, or seasoning (e.g., salt or spices).

(3) When nutrition labeling information is provided for more than one raw fruit, vegetable, or fish on signs, posters, brochures, notebooks, or leaflets, it may be presented in charts with horizontal or vertical columns or as a compilation of individual nutrition labels. Nutrition labeling that is presented in a linear display (see § 101.9(j)(13)(ii)(A)(2)) will not be considered to be in compliance. The heading "Nutrition Facts" must be in a type size larger than all other print in the nutrition label. The required information (i.e., headings, serving sizes, list of

nutrients, quantitative amounts by weight (except for vitamins and minerals), and percent of Daily Values (DV's) (except for sugars and protein) must be clearly presented and of sufficient type size and color contrast to be plainly legible, with numeric values for percent of DV highlighted in contrast to the quantitative amounts by weight and hairlines between all nutrients.

(i) Declaration of the number of servings per container need not be included in the nutrition labeling of raw fruits, vegetables, and fish.

(ii) Except for the statement "Percent Daily Values are based on a 2,000 calorie diet," the footnote required in §101.9(d)(9) is not required. However, when labeling is provided in brochures, notebooks, leaflets, or similar types of materials, retailers are encouraged to include the footnote.

(iii) When retailers provide nutrition labeling information for more than one raw fruit or vegetable on signs or posters or in brochures, notebooks, or leaflets, the listings for saturated fat, *trans* fat, and cholesterol may be omitted from the charts or individual nutrition labels if a footnote states that most fruits and vegetables provide negligible amounts of these nutrients, but that avocados contain 0.5 gram (g) of saturated fat per ounce (e.g., "Most fruits and vegetables provide negligible amounts of saturated fat, *trans* fat, and cholesterol; avocados provide 0.5 g of saturated fat per ounce"). The footnote also may contain information about the polyunsaturated and monounsaturated fat content of avocados.

(iv) When retailers provide nutrition labeling information for more than one raw fish on signs or posters or in brochures, notebooks, or leaflets, the listings for *trans* fat, dietary fiber, and sugars may be omitted from the charts or individual nutrition labels if the following footnote is used, "Fish provide negligible amounts of *trans* fat, dietary fiber, and sugars."

(4) When nutrition labeling is provided for individual raw fruits, vegetables, or fish on packages or on signs, posters, brochures, notebooks, or leaflets, it should be displayed in accordance with §101.9, except that the declaration of the number of servings per container need not be included. For individual labels provided by retailers on signs and posters, the footnote required in §101.9(d)(9) may be shortened to "Percent Daily Values are based on a 2,000 calorie diet."

(b) Nutrition label values provided by the Food and Drug Administration (FDA) in Appendices C and D to part 101 for the 20 most frequently consumed raw fruits, vegetables, and fish listed in §101.44 shall be used to ensure uniformity in declared values. FDA will publish proposed updates of the 20 most frequently consumed raw fruits, vegetables, and fish and nutrition label data for these foods (or a notice that the data sets have not changed from the previous publication) at least every 4 years in the FEDERAL REGISTER.

(1) The agency encourages the submission of data bases with new or additional nutrient data for any of the most frequently consumed raw fruits, vegetables, and fish to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, for review and evaluation. FDA may incorporate these data in the next revision of the nutrition labeling information for the top 20 raw fruits, vegetables, and fish.

(i) Guidance in the development of data bases may be found in the "FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases," available from the FDA Office of Food Labeling.

(ii) The submission to FDA 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, and statistical treatment of the data. Proposed quantitative label declarations may be included. The proposed values for declaration should be determined in accordance with the "FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases."

(2) [Reserved]

(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.

(2) Guidance in the development of data bases may be found in the "FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases."

(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 provision of § 101.30 of this chapter.

(ii) [Reserved]

[61 FR 42760, Aug. 16, 1996, as amended at 66 FR 56035, Nov. 6, 2001; 71 FR 42044, July 25, 2006]

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.

(2) The terms defined in paragraph (b)(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 "high" in paragraph (b)(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 broccoli in this product is high in vitamin C).

(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," "added," "extra," and "plus" 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) and 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 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 §101.2.

(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 15051, Mar. 31, 1994; 60 FR 17206, Apr. 5, 1995; 61 FR 11731, Mar. 22, 1996; 62 FR 31339, June 9, 1997; 62 FR 49867, 49880, Sept. 23, 1997; 63 FR 26980, May 15, 1998; 66 FR 17358, Mar. 30, 2001]

§ 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 (33⅓ 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 calories and the fat were reduced are declared in immediate proximity to the most prominent such claim, (e.g., "1/3 fewer calories and 50 percent less fat than our regular cheese cake");

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference food that it replaces (e.g., "lite cheesecake—200 calories, 4 grams (g) fat per serving; regular cheesecake—300 calories, 8 g 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; and

(iii) If the labeled food contains less than 40 calories or less than 3 g fat per reference amount customarily consumed, the percentage reduction for that nutrient need not be declared.

(4) A "light" claim may not be made on a food for which the reference food meets the definition of "low fat" and "low calorie."

(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

(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 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.

(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 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)(i); 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 ⅓ 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).

[58 FR 2413, Jan. 6, 1993; 58 FR 17342, Apr. 2, 1993, as amended at 60 FR 17206, Apr. 5, 1995]

§ 101.60 Nutrient content claims for the calorie content of foods.

(a) *General requirements.* A claim about the calorie or sugar content of a food may only be made on the label or in the labeling of a 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;

(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 (e.g., another protein 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 the 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)(A) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and does not provide more than 40 calories 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 does not provide more than 40 calories per reference amount customarily consumed and, except for sugar substitutes, 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).

(ii) If a food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the caloric 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., "celery, a low calorie 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 120 calories or less per 100 g; and

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

(4) The terms "reduced calorie," "reduced in calories," "calorie reduced," "fewer calories," "lower calorie," or "lower in calories" 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:

(i) 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

(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., reduced calorie cupcakes "33⅓ percent fewer calories than regular cupcakes"); and

(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)(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 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 sugar 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 sugar differs between the two foods are declared in immediate proximity to the most prominent such claim (e.g., "these corn flakes contain 25 percent less sugar than our sugar coated corn flakes"); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving with that of the reference food that it replaces (e.g., "Sugar content has been lowered from 8 g to 6 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.

(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.

[58 FR 2413, Jan. 6, 1993; 58 FR 17342, Apr. 2, 1993, as amended at 58 FR 44031, Aug. 18, 1993; 59 FR 394, Jan. 4, 1994; 60 FR 17206, Apr. 5, 1995; 62 FR 15342, Mar. 31, 1997; 62 FR 49881, Sept. 23, 1997]

§101.61 Nutrient content claims for the sodium content of foods.

(a) *General requirements.* A claim about the level of sodium or salt in a food may only be made on the label or in the 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) *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 grams (g) or greater than 2 tablespoons and contains 35 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)(1), 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 140 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)(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 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 meal 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 reference amount customarily consumed than an appropriate reference food as described in §101.13(j)(1).

(ii) As required for §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 labeled food are declared in immediate proximity to the most prominent such claim (e.g., "reduced sodium _____, 50 percent less sodium than regular _____"); and

(B) Quantitative information comparing the level of the sodium in the product per labeled serving with that of the reference food that it replaces (e.g., "Sodium content has been lowered from 300 to 150 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) 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.

(2) The terms "unsalted," "without added salt," and "no salt added" may be used on the label or in labeling of foods only if:

(i) No salt is added during processing;

(ii) The food that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the food is not sodium free, the statement, "not a sodium free food" or "not for control of sodium in the diet" appears 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.

(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.

[58 FR 2413, Jan. 6, 1993; 58 FR 17342, Apr. 2, 1993, as amended at 58 FR 44032, Aug. 18, 1993; 59 FR 394, Jan. 4, 1994; 60 FR 17206, Apr. 5, 1995]

§ 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 the 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 labeled 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

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—50 percent less fat than our regular brownies"); 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 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 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 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."

(6) The term "__ percent fat free" may be used on the label or in the labeling of foods, provided that:

(i) The food meets the criteria for "low fat" in paragraph (b)(2) or (b)(3) of this section;

(ii) The percent declared and the words "fat free" are in uniform type size; and

(iii) A "100 percent fat free" claim may be made only on foods that meet the criteria for "fat free" in paragraph (b)(1) of this section, that contain less than 0.5 g of fat per 100 g, and that contain no added fat.

(c) *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 fat and less than 0.5 g *trans* fatty acid 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 less 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:

(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."

(5) The terms defined in paragraph (c)(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 saturated 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 saturated fat Macaroni and Cheese, "33 percent less saturated fat per 3 oz than our regular Macaroni and Cheese").

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference food that it replaces (e.g., "Saturated fat content has been reduced from 2.5 g per 3 oz to 1.7 g per 3 oz.") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label in 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)(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 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, the per 50-g criterion refers to the "as prepared" form), or, in the case of meal products, 26.0 g or less total fat per labeled serving, or, in the case of main dish products, 19.5 g or less 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, 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 cutomarily 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 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 of 30 g or less or 2 tablespoons or less and contain 13 g or less of total fat per reference amount customarily consumed, per labeled serving, 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);

(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; 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) 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 (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)(i) 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 percent less cholesterol than _____); 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 55 mg to 30 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.

(iii) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a food if the nutrient content of the reference food meets the definition for "low cholesterol."

(5) The terms defined in paragraph (d)(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) 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; 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.

(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;

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

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

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

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

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

(e) *"Lean" and "extra lean" claims.* (1) The term "lean" may be used on the label or in labeling of foods except meal products as defined in §101.13(l) and main dish products as defined in §101.13(m) provided that the food is a seafood or game meat product and as packaged contains less than 10 g total fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g;

(2) The term defined in paragraph (e)(1) of this section may be used on the label or in labeling of a mixed dish not measurable with a cup as defined in §101.12(b) in table 2, provided that the food contains less than 8 g total fat, 3.5 g or less saturated fat and less than 80 mg cholesterol per reference amount customarily consumed;

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

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

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

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

[58 FR 2413, Jan. 6, 1993; 58 FR 17342, 17343, Apr. 2, 1993, as amended at 58 FR 44032, Aug. 18, 1993; 58 FR 60105, Nov. 15, 1993; 59 FR 394, Jan. 4, 1994; 60 FR 17207, Apr. 5, 1995; 61 FR 59001, Nov. 20, 1996; 63 FR 26980, May 15, 1998; 72 FR 1459, Jan. 12, 2007]

§ 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) This paragraph covers labeling claims that are implied nutrient content claims because they:

(i) Suggest that a food because of its nutrient content may help consumers maintain healthy dietary practices; and

(ii) Are made in connection with an explicit or implicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams of fat").

(2) You may use the term "healthy" or related terms (e.g., "health," "healthful," "healthfully," "healthfulness," "healthier," "healthiest," "healthily," and "healthiness") as an implied nutrient content claim on the label or in labeling of a food that is useful in creating a diet that is consistent with dietary recommendations if:

(i) The food meets the following conditions for fat, saturated fat, cholesterol, and other nutrients:

If the food is...	The fat level must be...	The saturated fat level must be...	The cholesterol level must be...	The food must contain...
(A) A raw fruit or vegetable	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(B) A single-ingredient or a mixture of frozen or canned fruits and vegetables[1]	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(C) An enriched cereal-grain product that conforms to a standard of identity in part 136, 137 or 139 of this chapter	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(D) A raw, single-ingredient seafood or game meat	Less than 5 grams (g) total fat per RA[2] and per 100 g	Less than 2 g saturated fat per RA and per 100 g	Less than 95 mg cholesterol per RA and per 100 g	At least 10 percent of the RDI[3] or the DRV[4] per RA of one or more of vitamin A, vitamin C, calcium, iron, protein, or fiber
(E) A meal product as defined in § 101.13(l) or a main dish product as defined in § 101.13(m)	Low fat as defined in § 101.62(b)(3)	Low saturated fat as defined in § 101.62(c)(3)	90 mg or less cholesterol per LS[5]	At least 10 percent of the RDI or DRV per LS of two nutrients (for a main dish product) or of three nutrients (for a meal product) of: vitamin A, vitamin C, calcium, iron, protein, or fiber
(F) A food not specifically listed in this table	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	At least 10 percent of the RDI or the DRV per RA of one or more of vitamin A, vitamin C, calcium, iron, protein or fiber

[1] May include ingredients whose addition does not change the nutrient profile of the fruit or vegetable.
[2] RA means Reference Amount Customarily Consumed per Eating Occasion (§ 101.12(b)).
[3] RDI means Reference Daily Intake (§ 101.9(c)(8)(iv)).
[4] DRV means Daily Reference Value (§ 101.9(c)(9)).
[5] LS means Labeled Serving, i.e., the serving size that is specified in the nutrition information on the product label (§ 101.9(b)).

(ii) The food meets the following conditions for sodium:

If the food is...	The sodium level must be...
(A) A food with a RA that is greater than 30 g or 2 tablespoons (tbsp.)	480 mg or less sodium per RA and per LS
(B) A food with a RA that is equal to or less than 30 g or 2 tbsp.	480 mg or less sodium per 50 g[1]
(C) A meal product as defined in § 101.13(l) or a main dish product as defined in § 101.13(m)	600 mg or less sodium per LS

[1] For dehydrated food that is typically reconstituted with water or a liquid that contains insignificant amounts per RA of all nutrients (as defined in § 101.9(f)(1)), the 50 g refers to the "prepared" form of the product.

(iii) The food complies with the definition and declaration requirements in this part 101 for any specific nutrient content claim on the label or in labeling, and

(iv) If you add a nutrient to the food specified in paragraphs (d)(2)(i)(D),

(d)(2)(i)(E), or (d)(2)(i)(F) of this section to meet the 10 percent requirement, that addition must be in accordance with the fortification policy for foods in §104.20 of this chapter.

[58 FR 2413, Jan. 6, 1993; 58 FR 17343, Apr. 2, 1993, as amended at 59 FR 394, Jan. 4, 1994; 59 FR 24249, May 10, 1994; 59 FR 50828, Oct. 6, 1994; 62 FR 49858, Sept. 23, 1997; 63 FR 14355, Mar. 25, 1998; 70 FR 56848, Sept. 29, 2005]

§ 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; and

(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, or the food will be deemed to be adulterated under section 402(b) of the act. The performance characteristics (e.g., physical properties, organoleptic characteristics, functional properties, shelf life) of 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 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 Nutritional Products, Labeling and Dietary Supplements (HFS–800)
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 AOAC 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 any corresponding 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,
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. A petition that has been denied, or has been deemed to be denied, without filing shall not be made available to the public. A filed petition shall be available to the public as provided under paragraph (g) of this section.

(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 rulemaking 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.

(Date)_____
Name of petitioner _____
Post office address _____
Subject of the petition _____
Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800)
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 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.

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:

(Date)_____
Name of petitioner _____
Post office address _____
Subject of the petition _____
Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800),
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 implied nutrient content claim and its proposed use in a brand name).

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

A. A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation under section 403(r)(2)(A)(i) of the act, and the brand name of which the implied claim is intended to be a part. The statement should address why the use of the brandname as proposed will not be misleading. It should address in particular what information is required to accompany the claim or other ways in which the claim meets the requirements of sections 201(n) and 403(a) of the act. The statement should provide examples of the types of foods on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food qualifies the food to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient should meet the requirements stated under petition format item C in paragraph (k)(1) of this section.

B. A detailed explanation, supported by any necessary data, of why use of the proposed brand name is requested. This item shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product 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. 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 _____

(2) Within 15 days of roooipt of tho po tition 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); 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) FDA will publish a notice of the petition in the FEDERAL REGISTER announcing its availability to the public and seeking comment on the petition. The petition shall be available to the public to the extent provided under paragraph (g) of this section. The notice shall allow 30 days for comments.

(4) Within 100 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 subsequently returned to the petitioner), FDA will:

(i) Notify the petitioner by letter of the agency's decision to grant the petitioner permission to use the proposed brand name if such use is not misleading, with any conditions or limitations on such use specified; or

(ii) 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. Should FDA not notify the petitioner of his decision on the petition within 100 days, the petition shall be considered to be granted.

(5) As soon as practicable following the granting of a petition, the Commissioner of Food and Drugs will publish a

notice in the FEDERAL REGISTER informing the public of such fact.

[58 FR 2413, Jan. 6, 1993; 58 FR 17343, Apr. 2, 1993, as amended at 58 FR 44033, Aug. 18, 1993; 62 FR 40598, July 29, 1997; 63 FR 26718, May 14, 1998; 63 FR 40024, July 27, 1998; 67 FR 9585, Mar. 4, 2002; 69 FR 16481, Mar. 30, 2004]

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 chapter, or were not subject to such requirements in accordance with §56.104 or §56.105, and a statement that they were conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(e) All data and information in a health claim petition are available for public disclosure after the notice of filing of petition is issued to the petitioner, except that clinical investigation reports, adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall only be available after deletion of:

(1) Names and any information that would identify the person using the product.

(2) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(f) Petitions for a health claim shall include the following data and be submitted in the following form:

(Date)_____
Name of petitioner _____
Post office address _____
Subject of the petition _____
Food and Drug Administration,
Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800),
5001 Campus Dr.,
College Park, MD 20740,

The undersigned, _____ submits this petition pursuant to section 403(r)(4) or 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act with respect to (statement of the substance and its health claim).

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

A. Preliminary requirements. A complete explanation of how the substance conforms to the requirements of §101.14(b) (21 CFR 101.14(b)). For petitions where the subject substance is a food ingredient or a component of a food ingredient, the petitioner should compile a comprehensive list of the specific ingredients that will be added to the food to supply the substance in the food bearing the health claim. For each such ingredient listed, the petitioner should state how the ingredient complies with the requirements of §101.14(b)(3)(ii), e.g., that its use is generally recognized as safe (GRAS),

listed as a food additive, or authorized by a prior sanction issued by the agency, and what the basis is for the GRAS claim, the food additive status, or prior sanctioned status.

B. Summary of scientific data. The summary of scientific data provides the basis upon which authorizing a health claim can be justified as providing the health benefit. The summary must establish that, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The summary shall state what public health benefit will derive from use of the claim as proposed. If the claim is intended for a specific group within the population, the summary shall specifically address nutritional needs of such group and shall include scientific data showing how the claim is likely to assist in meeting such needs.

The summary shall concentrate on the findings of appropriate review articles, National Institutes of Health consensus development conferences, and other appropriate resource materials. Issues addressed in the summary shall include answers to such questions as:

1. Is there an optimum level of the particular substance to be consumed beyond which no benefit would be expected?

2. Is there any level at which an adverse effect from the substance or from foods containing the substance occurs for any segment of the population?

3. Are there certain populations that must receive special consideration?

4. What other nutritional or health factors (both positive and negative) are important to consider when consuming the substance?

In addition, the summary of scientific data shall include a detailed analysis of the potential effect of the use of the proposed claim on food consumption, specifically any change due to significant alterations in eating habits and corresponding changes in nutrient intake resulting from such changes in food consumption. The latter item shall specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet.

If the claim is intended for a significant subpopulation within the general U.S. population, the 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.g., adolescents or the elderly).

If appropriate, the petition shall explain the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet.

Also, the summary shall demonstrate that the substance that is the subject of the proposed claim conforms to the definition of the term "substance" in § 101.14(a)(2).

C. Analytical data that show the amount of the substance that is present in representative foods that would be candidates to bear the claim should be obtained from representative samples using methods from the AOAC INTERNATIONAL (AOAC), where available. If no AOAC method is available, the petitioner shall submit the assay method used and data establishing the validity of the method for assaying the substance in food. The validation data should include a statistical analysis of the analytical and product variability.

D. Model health claim. One or more model health claims that represent label statements that may be used on a food label or in labeling for a food to characterize the relationship between the substance in a food to a disease or health-related condition that is justified by the summary of scientific data provided in section C of the petition. The model health claim shall include:

1. A brief capsulized statement of the relevant conclusions of the summary, and

2. A statement of how this substance helps the consumer to attain a total dietary pattern or goal associated with the health benefit that is provided.

E. The petition shall include the following attachments:

1. Copies of any computer literature searches done by the petitioner (e.g., Medline).

2. Copies of articles cited in the literature searches and other information as follows:

a. All information relied upon for the support of the health claim, including copies of publications or other information cited in review articles and used to perform meta-analyses.

b. All information concerning adverse consequences to any segment of the population (e.g., sensitivity to the substance).

c. All information pertaining to the U.S. population.

F. 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)

(g) The data specified under the several lettered headings should be submitted on separate pages or sets of pages, suitably identified. If such data have already been submitted with an earlier application from the petitioner

or any other final petition, the present petition may incorporate it by specific reference to the earlier petition.

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

(i) The petition shall be signed by the petitioner or by his/her attorney or agent, or (if a corporation) by an authorized official.

(j) *Agency action on the petition.* (1) 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 that the petition is undergoing agency review and that the petitioner will subsequently be notified of the agency's decision to file for comprehensive review or deny the petition.

(2) 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 for comprehensive review or denied. The agency will deny a petition without reviewing the information contained in "B. Summary of Scientific Data" if the information in "A. Preliminary Requirements" is inadequate in explaining how the substance conforms to the requirements of §101.14(b). If the petition is denied, the notification will state the reasons therefor, including justification of the rejection of any report from an authoritative scientific body of the U.S. Government. If filed, the date of the notification letter becomes the date of filing for the purposes of this regulation. 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 FDA and the petitioner. A petition that has been denied, or has been deemed to be denied, without filing will not be made available to the public. A filed petition will be available to the public to the extent provided under paragraph (e) of this section.

(3) 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 health claim will be published in the FEDERAL REGISTER. If the petition is denied, the notification will state the reasons therefor, including justification for the rejection of any report from an authoritative scientific body of the U.S. Government. FDA will publish the proposal to amend the regulations to provide for the requested use of the health 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 review.

(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.

(4)(i) Within 270 of the date of publication of the proposal, FDA will publish a final rule that either authorizes use of the health claim or explains why the agency has decided not to authorize one.

(ii) For cause, FDA may extend, no more than twice, the period in which it will publish a final rule; each such extension will be for no more than 90 days. FDA will publish a notice of each extension in the FEDERAL REGISTER. The document will state the basis for the extension, the length of the extension, and the date by which the final rule will be published, which date shall be within 540 days of the date of receipt of the petition.

[58 FR 2534, Jan. 6, 1993; 58 FR 17097, Apr. 1, 1993, as amended at 59 FR 425, Jan. 4, 1994; 62 FR 28232, May 22, 1997; 62 FR 40599, July 29, 1997; 63 FR 26719, May 14, 1998; 63 FR 40024, July 27, 1998; 66 FR 56035, Nov. 6, 2001]

§ 101.71 Health claims: claims not authorized.

Health claims not authorized for foods in conventional food form or for dietary supplements of vitamins, minerals, herbs, or other similar substances:

(a) Dietary fiber and cardiovascular disease.

(b) Zinc and immune function in the elderly.

[58 FR 2534, Jan. 6, 1993, as amended at 58 FR 2548, 2578, 2620, 2639, 2664, 2714, Jan. 6, 1993; 58 FR 17100, Apr. 1, 1993; 59 FR 437, Jan. 4, 1994; 65 FR 58918, Oct. 3, 2000]

§ 101.72 Health claims: calcium, vitamin D, and osteoporosis.

(a) *Relationship between calcium, vitamin D, and osteoporosis.* An inadequate intake of calcium or calcium and vitamin D contributes to low peak bone mass, which has been identified as one of many risk factors in the development of osteoporosis. Peak bone mass is the total quantity of bone present at maturity, and experts believe that it has the greatest bearing on whether a person will be at risk of developing osteoporosis and related bone fractures later in life. Another factor that influences total bone mass and susceptibility to osteoporosis is the rate of bone loss after skeletal maturity. Vitamin D is required for normal absorption of calcium and to prevent the occurrence of high serum parathyroid hormone (PTH) concentration, which stimulates mobilization of calcium from the skeleton and can lower bone mass. Calcium, along with vitamin D and several other nutrients, is required for normal bone mineralization. While vitamin D is required for optimal bone mineralization, it is more effective when calcium intake is adequate. An adequate intake of calcium and vitamin D is thought to exert a positive effect during adolescence and early adulthood in optimizing the amount of bone that is laid down. However, the upper limit of peak bone mass is genetically determined. The mechanism through which adequate intakes of calcium and vitamin D and optimal peak bone mass reduce the risk of osteoporosis is thought to be as follows. All persons lose bone with age. Hence, those with higher bone mass at maturity take longer to reach the critically reduced mass at which bones can fracture easily. The rate of bone loss after skeletal maturity also influences the amount of bone present at old age and can influence an individual's risk of developing osteoporosis. Maintenance of adequate intakes of calcium and vitamin D later in life is thought to be important in reducing the rate of bone loss particularly in the elderly and in women during the first decade following menopause, but a significant protective effect is also seen among men and younger women.

(b) *Significance of calcium or calcium and vitamin D.* Adequate calcium intake, or adequate calcium and vitamin D intake, is not the only recognized risk factor in the development of osteoporosis, which is a multifactorial bone disease. Maintenance of adequate calcium and vitamin D intakes throughout life is necessary to achieve optimal peak bone mass and to reduce the risk of osteoporosis in later life. However, vitamin D is most effective in this regard when calcium intake is adequate. Increasing intake of calcium has been shown to have beneficial effects on bone health independent of dietary vitamin D.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating calcium or, when appropriate, calcium and vitamin D with a reduced risk of osteoporosis may be made on the label or labeling of a food described in paragraphs (c)(2)(ii) and (d)(1) of this section, provided that:

(A) The claim makes clear the importance of adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, throughout life, in a healthful diet, are essential to reduce osteoporosis risk. The claim does not imply that adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, is the only recognized risk factor for the development of osteoporosis;

(B) The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate dietary calcium intake, or when appropriate, an adequate dietary calcium and vitamin D intake, throughout life.

(ii) *Nature of the food.* (A) The food shall meet or exceed the requirements for a "high" level of calcium as defined in § 101.54(b);

(B) The calcium content of the product shall be assimilable;

(C) Dietary supplements shall meet the United States Pharmacopeia (USP)

standards for disintegration and dissolution applicable to their component calcium salts, except that dietary supplements for which no USP standards exist shall exhibit appropriate assimilability under the conditions of use stated on the product label;

(D) A food or total daily recommended supplement intake shall not contain more phosphorus than calcium on a weight per weight basis.

(d) *Optional information.* (1) The claim may include the term "vitamin D" if the food meets or exceeds the requirements for a "high" level of vitamin D as defined in §101.54(b);

(2) The claim may include information from paragraphs (a) and (b) of this section.

(3) The claim may make reference to physical activity.

(4) The claim may include information on the number of people in the United States, including the number of people in certain subpopulations in the United States, who have osteoporosis or low bone density. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or the National Osteoporosis Foundation.

(5) The claim may state that the role of adequate calcium intake, or when appropriate, the role of adequate calcium and vitamin D intake, throughout life is linked to reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and early adulthood. The phrase "build and maintain good bone health" may be used to convey the concept of optimizing peak bone mass. The claim may also state that adequate intake of calcium, or when appropriate, adequate intake of calcium and vitamin D, is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss for persons with a family history of the disease, post-menopausal women, and elderly men and women.

(e) *Model health claims.* The following model health claims may be used in food labeling to describe the relationship between calcium and osteoporosis:

Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.

Adequate calcium as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.

(f) *Model additional health claims for calcium and vitamin D.* The following model health claims may be used in food labeling to describe the relationship between calcium, vitamin D, and osteoporosis:

Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.

Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.

[73 FR 56486, Sept. 29, 2008]

§101.73 Health claims: dietary lipids and cancer.

(a) *Relationship between fat and cancer.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include a family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) Among dietary factors, the strongest positive association has been found between total fat intake and risk of some types of cancer. Based on the totality of the publicly available scientific evidence, there is significant scientific agreement among experts, qualified by training and experience to evaluate such evidence, that diets high in total fat are associated with an increased cancer risk. Research to date, although not conclusive, demonstrates that the total amount of fats, rather than any specific type of fat, is positively associated with cancer risk. The mechanism by which total fat affects cancer has not yet been established.

(3) A question that has been the subject of considerable research is whether

the effect of fat on cancer is site-specific. Neither human nor animal studies are consistent in the association of fat intake with specific cancer sites.

(4) Another question that has been raised is whether the association of total fat intake to cancer risk is independently associated with energy intakes, or whether the association of fat with cancer risk is the result of the higher energy (caloric) intake normally associated with high fat intake. FDA has concluded that evidence from both animal and human studies indicates that total fat intake alone, independent of energy intake, is associated with cancer risk.

(b) *Significance of the relationship between fat intake and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and high in calories. The average U.S. diet is estimated to contain 36 to 37 percent of calories from total fat. Current dietary guidelines from the Federal Government and other national health professional organizations recommend that dietary fat intake be reduced to a level of 30 percent or less of energy (calories) from total fat. In order to reduce intake of total fat, individuals should choose diets which are high in vegetables, fruits, and grain products (particularly whole grain products), choose lean cuts of meats, fish, and poultry, substitute low-fat dairy products for higher fat products, and use fats and oils sparingly.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets low in fat with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat "may" or "might" reduce the risk of some cancers;

(B) In specifying the disease, the claim uses the following terms: "some types of cancer" or "some cancers";

(C) In specifying the nutrient, the claim uses the term "total fat" or "fat";

(D) The claim does not specify types of fat or fatty acid that may be related to the risk of cancer;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat; and

(F) The claim indicates that the development of cancer depends on many factors.

(ii) *Nature of the food.* The food shall meet all of the nutrient content requirements of § 101.62 for a "low fat" food; except that fish and game meats (i.e., deer, bison, rabbit, quail, wild turkey, geese, ostrich) may meet the requirements for "extra lean" in § 101.62.

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) The claim may include information from paragraphs (a) and (b) of this section which summarize the relationship between dietary fat and cancer and the significance of the relationship.

(3) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office.

(4) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to describe the relationship between dietary fat and cancer:

(1) Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.

(2) Eating a healthful diet low in fat may help reduce the risk of some types of cancers. Development of cancer is associated with many factors, including a family history of the disease, cigarette smoking, and what you eat.

[58 FR 2801, Jan. 6, 1993; 58 FR 17343, Apr. 2, 1993]

§ 101.74 Health claims: sodium and hypertension.

(a) *Relationship between sodium and hypertension (high blood pressure).* (1) Hypertension, or high blood pressure, generally means a systolic blood pressure of greater than 140 millimeters of mercury (mm Hg) or a diastolic blood pressure of greater than 90 mm Hg. Normotension, or normal blood pressure, is a systolic blood pressure below 140 mm Hg and diastolic blood pressure below 90 mm Hg. Sodium is specified here as the chemical entity or electrolyte "sodium" and is distinguished from sodium chloride, or salt, which is 39 percent sodium by weight.

(2) The scientific evidence establishes that diets high in sodium are associated with a high prevalence of hypertension or high blood pressure and with increases in blood pressure with age, and that diets low in sodium are associated with a low prevalence of hypertension or high blood pressure and with a low or no increase of blood pressure with age.

(b) *Significance of sodium in relation to high blood pressure.* (1) High blood pressure is a public health concern primarily because it is a major risk factor for mortality from coronary heart disease and stroke. Early management of high blood pressure is a major public health goal that can assist in reducing mortality associated with coronary heart disease and stroke. There is a continuum of mortality risk that increases as blood pressures rise. Individuals with high blood pressure are at greatest risk, and individuals with moderately high, high normal, and normal blood pressure are at steadily decreasing risk. The scientific evidence indicates that reducing sodium intake lowers blood pressure and associated risks in many but not all hypertensive individuals. There is also evidence that reducing sodium intake lowers blood pressure and associated risks in many but not all normotensive individuals as well.

(2) The populations at greatest risk for high blood pressure, and those most likely to benefit from sodium reduction, include those with family histories of high blood pressure, the elderly, males because they develop hypertension earlier in life than females, and black males and females. Although some population groups are at greater risk than others, high blood-pressure is a disease of public health concern for all population groups. Sodium intake, alcohol consumption, and obesity are identified risk factors for high blood pressure.

(3) Sodium intakes exceed recommended levels in almost every group in the United States. One of the major public health recommendations relative to high blood pressure is to decrease consumption of salt. On a population-wide basis, reducing the average sodium intake would have a small but significant effect on reducing the average blood pressure, and, consequently, reducing mortality from coronary heart disease and stroke.

(4) Sodium is an essential nutrient, and experts have recommended a safe minimum level of 500 milligrams (mg) sodium per day and an upper level of 2,400 mg sodium per day, the FDA Daily Value for sodium.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets low in sodium with reduced risk of high blood pressure may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in sodium "may" or "might" reduce the risk of high blood pressure;

(B) In specifying the disease, the claim uses the term "high blood pressure";

(C) In specifying the nutrient, the claim uses the term "sodium";

(D) The claim does not attribute any degree of reduction in risk of high blood pressure to diets low in sodium; and

(E) The claim indicates that development of high blood pressure depends on many factors.

(ii) *Nature of the food.* The food shall meet all of the nutrient content requirements of §101.61 for a "low sodium" food.

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for development of high blood pressure in addition to dietary sodium consumption: Family history of high blood pressure, growing older, alcohol consumption, and excess weight.

(2) The claim may include information from paragraphs (a) and (b) of this section, which summarizes the relationship between dietary sodium and high blood pressure and the significance of the relationship.

(3) The claim may include information on the number of people in the United States who have high blood pressure. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Health and Human Services (DHHS) and U.S. Department of Argiculture (USDA), Government Printing Office.

(4) The claim may indicate that it is consistent with "Nutrition and Your Health: U.S. Dietary Guidelines for Americans, DHHS and USDA, Government Printing Office.

(5) In specifying the nutrient, the claim may include the term "salt" in addition to the term "sodium."

(6) In specifying the disease, the claim may include the term "hypertension" in addition to the term "high blood pressure."

(7) The claim may state that individuals with high blood pressure should consult their physicians for medical advice and treatment. If the claim defines high or normal blood pressure, then the health claim must state that individuals with high blood pressure should consult their physicians for medical advice and treatment.

(e) *Model health claims.* The following are model health claims that may be used in food labeling to describe the relationship between dietary sodium and high blood pressure:

(1) Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.

(2) Development of hypertension or high blood pressure depends on many factors. [This product] can be part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure.

[58 FR 2836, Jan. 6, 1993; 58 FR 17100, Apr. 1, 1993]

§ 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.

(a) *Relationship between dietary saturated fat and cholesterol and risk of coronary heart disease.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total- and low density lipoprotein (LDL)- cholesterol levels are major modifiable risk factors in the development of coronary heart disease. High coronary heart disease rates occur among people with high blood cholesterol levels of 240 milligrams/decaliter (mg/dL) (6.21 millimoles per liter (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. Dietary lipids (fats) include fatty acids and cholesterol. Total fat, commonly referred to as fat, is composed of saturated fat (fatty acids containing no double bonds), and monounsaturated and polyunsaturated fat (fatty acids containing one or more double bonds).

(2) The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of coronary heart disease. Diets low in saturated fat and cholesterol are associated with decreased levels of blood total- and LDL-cholesterol, and thus, with decreased risk of developing coronary heart disease.

(b) *Significance of the relationship between dietary saturated fat and cholesterol and risk of coronary heart disease.* (1) Coronary heart disease is a major public health concern in the United States, primarily because it accounts for more deaths than any other disease or group of diseases. Early management of risk factors for coronary heart disease is a major public health goal that can assist in reducing risk of coronary heart disease. There is a continuum of mortality risk from coronary heart disease that increases with increasing levels of blood LDL-cholesterol. Individuals with high blood LDL-cholesterol are at greatest risk. A larger number of individuals with more moderately elevated cholesterol also have increased risk of coronary events; such individuals comprise a substantial proportion of the adult U.S. population. The scientific evidence indicates that reducing saturated fat and cholesterol intakes lowers blood LDL-cholesterol and risk of heart disease in most individuals. There is also evidence that reducing saturated fat and cholesterol intakes in persons with blood cholesterol levels in the normal range also reduces risk of heart disease.

(2) Other risk factors for coronary heart disease include a family history of heart disease, high blood pressure, diabetes, cigarette smoking, obesity (body weight 30 percent greater than ideal body weight), and lack of regular physical exercise.

(3) Intakes of saturated fat exceed recommended levels in many people in the United States. Intakes of cholesterol are, on average, at or above recommended levels. One of the major public health recommendations relative to coronary heart disease risk is to consume less than 10 percent of calories from saturated fat, and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day.

(c) *Requirements.* (1) All requirements set forth in §101.14 shall be met, except §101.14(e)(6) with respect to a raw fruit or vegetable.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets low in saturated fat and cholesterol with reduced risk of coronary heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section provided that:

(A) The claim states that diets low in saturated fat and cholesterol "may" or "might" reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the terms "heart disease" or "coronary heart disease;"

(C) In specifying the nutrient, the claim uses the terms "saturated fat" and "cholesterol" and lists both;

(D) The claim does not attribute any degree of risk reduction for coronary heart disease to diets low in dietary saturated fat and cholesterol; and

(E) The claim states that coronary heart disease risk depends on many factors.

(ii) *Nature of the food.* (A) The food shall meet all of the nutrient content requirements of §101.62 for a "low saturated fat" and "low cholesterol" food.

(B) The food shall meet the nutrient content requirements of §101.62 for a "low fat" food, unless it is a raw fruit or vegetable; except that fish and game meats (*i.e.*, deer, bison, rabbit, quail, wild turkey, geese, and ostrich) may meet the requirements for "extra lean" in §101.62.

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors in addition to saturated fat and cholesterol about which there is general scientific agreement that they are major risk factors for this disease: A family history of coronary heart disease, elevated blood total and LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, diabetes, and physical inactivity.

(2) The claim may indicate that the relationship of saturated fat and cholesterol to heart disease is through the intermediate link of "blood cholesterol" or "blood total- and LDL cholesterol."

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between dietary saturated fat and cholesterol and risk of coronary heart disease, and the significance of the relationship.

(4) In specifying the nutrients, the claim may include the term "total fat" in addition to the terms "saturated fat" and "cholesterol".

(5) The claim may include information on the number of people in the United States who have coronary heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Health and Human Services (DHHS) and U.S. Department of Agriculture (USDA), Government Printing Office.

(6) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," DHHS and USDA, Government Printing Office.

(7) The claim may state that individuals with elevated blood total- or LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- or LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

(e) *Model health claims.* The following are model health claims that may be used in food labeling to describe the relationship between dietary saturated fat and cholesterol and risk of heart disease:

(1) While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease;

(2) Development of heart disease depends upon many factors, but its risk may be reduced by diets low in saturated fat and cholesterol and healthy lifestyles;

(3) Development of heart disease depends upon many factors, including a family history of the disease, high blood LDL-cholesterol, diabetes, high blood pressure, being overweight, cigarette smoking, lack of exercise, and the type of dietary pattern. A healthful diet low in saturated fat, total fat, and cholesterol, as part of a healthy lifestyle, may lower blood cholesterol levels and may reduce the risk of heart disease;

(4) Many factors, such as a family history of the disease, increased blood- and LDL-cholesterol levels, high blood pressure, cigarette smoking, diabetes, and being overweight, contribute to developing heart disease. A diet low in saturated fat, cholesterol, and total fat may help reduce the risk of heart disease; and

(5) Diets low in saturated fat, cholesterol, and total fat may reduce the risk of heart disease. Heart disease is dependent upon many factors, including diet, a family history of the disease, elevated blood LDL-cholesterol levels, and physical inactivity.

[58 FR 2757, Jan. 6, 1993, as amended at 81 FR 91722, Dec. 19, 2016]

§ 101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer.

(a) *Relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and cancer risk.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include: A family history of a specific type of cancer, cigarette smoking, overweight and obesity, alcohol consumption, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) The scientific evidence establishes that diets low in fat and high in fiber-containing grain products, fruits, and vegetables are associated with a reduced risk of some types of cancer. Although the specific role of total dietary fiber, fiber components, and the multiple nutrients and other substances contained in these foods are not yet fully understood, many studies have shown that diets low in fat and high in fiber-containing foods are associated with reduced risk of some types of cancer.

(b) *Significance of the relationship between consumption of diets low in fat and high in fiber-containing grain products, fruits, and vegetables and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The

overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and low in grain products, fruits, and vegetables. Studies in various parts of the world indicate that populations who habitually consume a diet high in plant foods have lower risks of some cancers. These diets generally are low in fat and rich in many nutrients, including, but not limited to, dietary fiber. Current dietary guidelines from Federal government agencies and nationally recognized health professional organizations recommend decreased consumption of fats (less than 30 percent of calories), maintenance of desirable body weight, and increased consumption of fruits and vegetables (five or more servings daily), and grain products (six or more servings daily).

(c) *Requirements.* (1) All requirements set forth in §101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets low in fat and high in fiber-containing grain products, fruits, and vegetables with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat and high in fiber-containing grain products, fruits, and vegetables "may" or "might" reduce the risk of some cancers;

(B) In specifying the disease, the claim uses the following terms: "some types of cancer," or "some cancers";

(C) The claim is limited to grain products, fruits, and vegetables that contain dietary fiber;

(D) The claim indicates that development of cancer depends on many factors;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat and high in fiber-containing grain products, fruits, and vegetables;

(F) In specifying the dietary fiber component of the labeled food, the claim uses the term "fiber", "dietary fiber" or "total dietary fiber"; and

(G) The claim does not specify types of dietary fiber that may be related to risk of cancer.

(ii) *Nature of the food.* (A) The food shall be or shall contain a grain product, fruit, or vegetable.

(B) The food shall meet the nutrient content requirements of §101.62 for a "low fat" food.

(C) The food shall meet, without fortification, the nutrient content requirements of §101.54 for a "good source" of dietary fiber.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables, and some types of cancer and the significance of the relationship.

(2) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, overweight and obesity, alcohol consumption, ultraviolet or ionizing radiation, exposure to cancer causing chemicals, and dietary factors.

(3) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office.

(4) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and cancer risk:

(1) Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.

(2) Development of cancer depends on many factors. Eating a diet low in fat and high in grain products, fruits, and

vegetables that contain dietary fiber may reduce your risk of some cancers.

[58 FR 2548, Jan. 6, 1993]

§ 101.77 Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.

(a) *Relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total- and low density lipoprotein (LDL)- cholesterol levels are major modifiable risk factors in the development of coronary heart disease. High coronary heart disease rates occur among people with high blood cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. Dietary lipids (fats) include fatty acids and cholesterol. Total fat, commonly referred to as fat, is composed of saturated fat (fatty acids containing no double bonds), and monounsaturated and polyunsaturated fat (fatty acids containing one or more double bonds).

(2) The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of coronary heart disease. Diets low in saturated fat and cholesterol are associated with decreased levels of blood total- and LDL-cholesterol, and thus, with decreased risk of developing coronary heart disease.

(3) Populations with relatively low blood cholesterol levels tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in fruits, vegetables, and grain products. Although the specific roles of these plant foods are not yet fully understood, many studies have shown that diets high in plant foods are associated with reduced risk of coronary heart disease. These studies correlate diets rich in fruits, vegetables, and grain products and nutrients from these diets, such as some types of fiber, with reduced coronary heart disease risk. Persons consuming these diets frequently have high intakes of dietary fiber, particularly soluble fibers. Currently, there is not scientific agreement as to whether a particular type of soluble fiber is beneficial, or whether the observed protective effects of fruits, vegetables, and grain products against heart disease are due to other components, or a combination of components, in these diets, including, but not necessarily limited to, some types of soluble fiber, other fiber components, other characteristics of the complex carbohydrate content of these foods, other nutrients in these foods, or displacement of saturated fat and cholesterol from the diet.

(b) *Significance of the relationship between diets low in saturated fat and cholesterol, and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.* (1) Coronary heart disease is a major public health concern in the United States, primarily because it accounts for more deaths than any other disease or group of diseases. Early management of risk factors for coronary heart disease is a major public health goal that can assist in reducing risk of coronary heart disease. There is a continuum of mortality risk from coronary heart disease that increases with increasing levels of blood LDL-cholesterol. Individuals with high blood LDL-cholesterol are at greatest risk. A larger number of individuals with more moderately elevated cholesterol also have increased risk of coronary events; such individuals comprise a substantial proportion of the adult U.S. population. The scientific evidence indicates that reducing saturated fat and cholesterol intakes lowers blood LDL-cholesterol and risk of heart disease in most individuals, including persons with blood cholesterol levels in the normal range. Additionally, consuming diets high in fruits,

vegetables, and grain products, foods that contain soluble fiber, may be a useful adjunct to a low saturated fat and low cholesterol diet.

(2) Other risk factors for coronary heart disease include a family history of heart disease, high blood pressure, diabetes, cigarette smoking, obesity (body weight 30 percent greater than ideal body weight), and lack of regular physical exercise.

(3) Intakes of saturated fat exceed recommended levels in many people in the United States. Intakes of cholesterol are, on average, at or above recommended levels. Intakes of fiber-containing fruits, vegetables, and grain products are about half of recommended intake levels. One of the major public health recommendations relative to coronary heart disease risk is to consume less than 10 percent of calories from saturated fat, and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Recommended total dietary fiber intakes are about 25 grams (g) daily, of which about 25 percent (about 6 g) should be soluble fiber.

(4) Current dietary guidance recommendations encourage decreased consumption of dietary fat, especially saturated fat and cholesterol, and increased consumption of fiber-rich foods to help lower blood LDL-cholesterol levels. Results of numerous studies have shown that fiber-containing fruits, vegetables, and grain products can help lower blood LDL-cholesterol.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber "may" or "might" reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the following terms: "heart disease" or "coronary heart disease;"

(C) The claim is limited to those fruits, vegetables, and grains that contain fiber;

(D) In specifying the dietary fiber, the claim uses the term "fiber," "dietary fiber," "some types of dietary fiber," "some dietary fibers," or "some fibers;" the term "soluble fiber" may be used in addition to these terms;

(E) In specifying the fat component, the claim uses the terms "saturated fat" and "cholesterol;" and

(F) The claim indicates that development of heart disease depends on many factors; and

(G) The claim does not attribute any degree of risk reduction for coronary heart disease to diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber.

(ii) *Nature of the food.* (A) The food shall be or shall contain a fruit, vegetable, or grain product.

(B) The food shall meet the nutrient content requirements of § 101.62 for a "low saturated fat," "low cholesterol," and "low fat" food.

(C) The food contains, without fortification, at least 0.6 g of soluble fiber per reference amount customarily consumed;

(D) The content of soluble fiber shall be declared in the nutrition information panel, consistent with § 101.9(c)(6)(i)(A).

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of coronary heart disease, elevated blood-, total- and LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, diabetes, and physical inactivity.

(2) The claim may indicate that the relationship of diets low in saturated fat and cholesterol, and high in fruits, vegetables, and grain products that contain fiber to heart disease is through the intermediate link of "blood cholesterol" or "blood total- and LDL-cholesterol."

(3) The claim may include information from paragraphs (a) and (b) of this

section, which summarize the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber and coronary heart disease, and the significance of the relationship.

(4) In specifying the nutrients, the claim may include the term "total fat" in addition to the terms "saturated fat" and "cholesterol."

(5) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(6) The claim may state that individuals with elevated blood total- and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, GPO.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain soluble fiber:

(1) Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.

(2) Development of heart disease depends on many factors. Eating a diet low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber may lower blood cholesterol levels and reduce your risk of heart disease.

[58 FR 2578, Jan. 6, 1993]

§ 101.78 Health claims: fruits and vegetables and cancer.

(a) *Relationship between substances in diets low in fat and high in fruits and vegetables and cancer risk.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include a family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) Although the specific roles of the numerous potentially protective substances in plant foods are not yet understood, many studies have shown that diets high in plant foods are associated with reduced risk of some types of cancers. These studies correlate diets rich in fruits and vegetables and nutrients from these diets, such as vitamin C, vitamin A, and dietary fiber, with reduced cancer risk. Persons consuming these diets frequently have high intakes of these nutrients. Currently, there is not scientific agreement as to whether the observed protective effects of fruits and vegetables against cancer are due to a combination of the nutrient components of diets rich in fruits and vegetables, including but not necessarily limited to dietary fiber, vitamin A (as beta-carotene) and vitamin C, to displacement of fat from such diets, or to intakes of other substances in these foods which are not nutrients but may be protective against cancer risk.

(b) *Significance of the relationship between consumption of diets low in fat and high in fruits and vegetables and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and low in fruits and vegetables. Studies in various parts of the world indicate that populations who habitually consume a diet high in plant foods have lower risks of some cancers. These diets generally are low in fat and rich in many nutrients, including, but not limited to, dietary fiber, vitamin A (as beta-carotene), and vitamin C. Current dietary guidelines from Federal Government agencies and nationally recognized health professional organizations recommend decreased consumption of fats (less than 30 percent of calories), maintenance of desirable body weight, and increased consumption of fruits and vegetables (5 or more servings daily), particularly those fruits and vegetables which contain dietary fiber, vitamin A, and vitamin C.

(c) *Requirements.* (1) All requirements set forth in §101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating substances in diets low in fat and high in fruits and vegetables with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat and high in fruits and vegetables "may" or "might" reduce the risk of some cancers;

(B) In specifying the disease, the claim uses the following terms: "some types of cancer", or "some cancers";

(C) The claim characterizes fruits and vegetables as foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber;

(D) The claim characterizes the food bearing the claim as containing one or more of the following, for which the food is a good source under §101.54: dietary fiber, vitamin A, or vitamin C;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat and high in fruits and vegetables;

(F) In specifying the fat component of the labeled food, the claim uses the term "total fat" or "fat";

(G) The claim does not specify types of fats or fatty acids that may be related to risk of cancer;

(H) In specifying the dietary fiber component of the labeled food, the claim uses the term "fiber", "dietary fiber", or "total dietary fiber";

(I) The claim does not specify types of dietary fiber that may be related to risk of cancer; and

(J) The claim indicates that development of cancer depends on many factors.

(ii) *Nature of the food.* (A) The food shall be or shall contain a fruit or vegetable.

(B) The food shall meet the nutrient content requirements of §101.62 for a "low fat" food.

(C) The food shall meet, without fortification, the nutrient content requirements of §101.54 for a "good source" of at least one of the following: vitamin A, vitamin C, or dietary fiber.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in fat and high in fruits and vegetables and some types of cancer and the significance of the relationship.

(2) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(3) The claim may use the word "beta-carotene" in parentheses after the term vitamin A, provided that the vitamin A in the food bearing the claim is beta-carotene.

(4) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (DHHS), Government Printing Office.

(5) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between substances in diets low in fat and high in fruits and vegetables and cancer:

(1) Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C, and it is a good source of dietary fiber.

(2) Development of cancer depends on many factors. Eating a diet low in fat and high in fruits and vegetables, foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber, may reduce your risk of some cancers. Oranges, a food low in fat, are a good source of fiber and vitamin C.

[58 FR 2639, Jan. 6, 1993]

§ 101.79 Health claims: Folate and neural tube defects.

(a) *Relationship between folate and neural tube defects*—(1) *Definition.* Neural tube defects are serious birth defects of the brain or spinal cord that can result in infant mortality or serious disability. The birth defects anencephaly and spina bifida are the most common forms of neural tube defects and account for about 90 percent of these defects. These defects result from failure of closure of the covering of the brain or spinal cord during early embryonic development. Because the neural tube forms and closes during early pregnancy, the defect may occur before a woman realizes that she is pregnant.

(2) *Relationship.* The available data show that diets adequate in folate may reduce the risk of neural tube defects. The strongest evidence for this relationship comes from an intervention study by the Medical Research Council of the United Kingdom that showed that women at risk of recurrence of a neural tube defect pregnancy who consumed a supplement containing 4 milligrams (mg)(4,000 micrograms (mcg)) folic acid daily before conception and continuing into early pregnancy had a reduced risk of having a child with a neural tube defect. (Products containing this level of folic acid are drugs). In addition, based on its review of a Hungarian intervention trial that reported periconceptional use of a multivitamin and multimineral preparation containing 800 mcg (0.8 mg) of folic acid, and its review of the observational studies that reported periconceptional use of multivitamins containing 0 to 1,000 mcg of folic acid, the Food and Drug Administration concluded that most of these studies had results consistent with the conclusion that folate, at levels attainable in usual diets, may reduce the risk of neural tube defects.

(b) *Significance of folate*—(1) *Public health concern.* Neural tube defects occur in approximately 0.6 of 1,000 live births in the United States (i.e., approximately 6 of 10,000 live births; about 2,500 cases among 4 million live births annually). Neural tube defects are believed to be caused by many factors. The single greatest risk factor for a neural tube defect-affected pregnancy is a personal or family history of a pregnancy affected with a such a defect. However, about 90 percent of infants with a neural tube defect are born to women who do not have a family history of these defects. The available evidence shows that diets adequate in folate may reduce the risk of neural tube defects but not of other birth defects.

(2) *Populations at risk.* Prevalence rates for neural tube defects have been reported to vary with a wide range of factors including genetics, geography, socioeconomic status, maternal birth cohort, month of conception, race, nutrition, and maternal health, including maternal age and reproductive history. Women with a close relative (i.e., sibling, niece, nephew) with a neural tube defect, those with insulin-dependent diabetes mellitus, and women with seizure disorders who are being treated with valproic acid or carbamazepine are at significantly increased risk compared with women without these characteristics. Rates for neural tube defects vary within the United States, with lower rates observed on the west coast than on the east coast.

(3) *Those who may benefit.* Based on a synthesis of information from several studies, including those which used multivitamins containing folic acid at

a daily dose level of ≥400 mcg (≥0.4 mg), the Public Health Service has inferred that folate alone at levels of 400 mcg (0.4 mg) per day may reduce the risk of neural tube defects. The protective effect found in studies of lower dose folate measured by the reduction in neural tube defect incidence, ranges from none to substantial; a reasonable estimate of the expected reduction in the United States is 50 percent. It is expected that consumption of adequate folate will avert some, but not all, neural tube defects. The underlying causes of neural tube defects are not known. Thus, it is not known what proportion of neural tube defects will be averted by adequate folate consumption. From the available evidence, the Public Health Service estimates that there is the potential for averting 50 percent of cases that now occur (i.e., about 1,250 cases annually). However, until further research is done, no firm estimate of this proportion will be available.

(c) *Requirements.* The label or labeling of food may contain a folate/neural tube defect health claim provided that:

(1) *General requirements.* The health claim for a food meets all of the general requirements of §101.14 for health claims, except that a food may qualify to bear the health claim if it meets the definition of the term "good source."

(2) *Specific requirements*—(i) *Nature of the claim*—(A) *Relationship.* A health claim that women who are capable of becoming pregnant and who consume adequate amounts of folate daily during their childbearing years may reduce their risk of having a pregnancy affected by spina bifida or other neural tube defects may be made on the label or labeling of food provided that:

(B) *Specifying the nutrient.* In specifying the nutrient, the claim shall use the terms "folate," "folic acid," "folacin," "folate, a B vitamin," "folic acid, a B vitamin," or "folacin, a B vitamin."

(C) *Specifying the condition.* In specifying the health- related condition, the claim shall identify the birth defects as "neural tube defects," "birth defects spina bifida or anencephaly," "birth defects of the brain or spinal cord anencephaly or spina bifida," "spina bifida and anencephaly, birth defects of the brain or spinal cord," "birth defects of the brain or spinal cord;" or "brain or spinal cord birth defects."

(D) *Multifactorial nature.* The claim shall not imply that folate intake is the only recognized risk factor for neural tube defects.

(E) *Reduction in risk.* The claim shall not attribute any specific degree of reduction in risk of neural tube defects from maintaining an adequate folate intake throughout the childbearing years. The claim shall state that some women may reduce their risk of a neural tube defect pregnancy by maintaining adequate intakes of folate during their childbearing years. Optional statements about population-based estimates of risk reduction may be made in accordance with paragraph (c)(3)(vi) of this section.

(F) *Safe upper limit of daily intake.* Claims on foods that contain more than 100 percent of the Daily Value (DV) (400 mcg) when labeled for use by adults and children 4 or more years of age, or 800 mcg when labeled for use by pregnant or lactating women) shall identify the safe upper limit of daily intake with respect to the DV. The safe upper limit of daily intake value of 1,000 mcg (1 mg) may be included in parentheses.

(G) The claim shall state that folate needs to be consumed as part of a healthful diet.

(ii) *Nature of the food*—(A) *Requirements.* The food shall meet or exceed the requirements for a "good source" of folate as defined in §101.54;

(B) *Dietary supplements.* Dietary supplements shall meet the United States Pharmacopeia (USP) standards for disintegration and dissolution, except that if there are no applicable USP standards, the folate in the dietary supplement shall be shown to be bioavailable under the conditions of use stated on the product label.

(iii) *Limitation.* The claim shall not be made on foods that contain more than 100 percent of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D per serving or per unit.

(iv) *Nutrition labeling.* The nutrition label shall include information about the amount of folate in the food. This information shall be declared after the declaration for iron if only the levels of vitamin A, vitamin C, calcium, and

iron are provided, or in accordance with §101.9 (c)(8) and (c)(9) if other optional vitamins or minerals are declared.

(3) *Optional information*—(i) *Risk factors.* The claim may specifically identify risk factors for neural tube defects. Where such information is provided, it may consist of statements from §101.79(b)(1) or (b)(2) (e.g., Women at increased risk include those with a personal history of a neural tube defect-affected pregnancy, those with a close relative (i.e., sibling, niece, nephew) with a neural tube defect; those with insulin-dependent diabetes mellitus; those with seizure disorders who are being treated with valproic acid or carbamazepine) or from other parts of this paragraph (c)(3)(i).

(ii) *Relationship between folate and neural tube defects.* The claim may include statements from paragraphs (a) and (b) of this section that summarize the relationship between folate and neural tube defects and the significance of the relationship except for information specifically prohibited from the claim.

(iii) *Personal history of a neural tube defect-affected pregnancy.* The claim may state that women with a history of a neural tube defect pregnancy should consult their physicians or health care providers before becoming pregnant. If such a statement is provided, the claim shall also state that all women should consult a health care provider when planning a pregnancy.

(iv) *Daily value.* The claim may identify 100 percent of the DV (100% DV; 400 mcg) for folate as the target intake goal.

(v) *Prevalence.* The claim may provide estimates, expressed on an annual basis, of the number of neural tube defect-affected births among live births in the United States. Current estimates are provided in §101.79(b)(1), and are approximately 6 of 10,000 live births annually (i.e., about 2,500 cases among 4 million live births annually). Data provided in §101.79(b)(1) shall be used, unless more current estimates from the U.S. Public Health Service are available, in which case the latter may be cited.

(vi) *Reduction in risk.* An estimate of the reduction in the number of neural tube defect-affected births that might occur in the United States if all women consumed adequate folate throughout their childbearing years may be included in the claim. Information contained in paragraph (b)(3) of this section may be used. If such an estimate (i.e., 50 percent) is provided, the estimate shall be accompanied by additional information that states that the estimate is population-based and that it does not reflect risk reduction that may be experienced by individual women.

(vii) *Diets adequate in folate.* The claim may identify diets adequate in folate by using phrases such as "Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements." or "Adequate amounts of folate can be obtained from diets rich in fruits, dark green leafy vegetables, legumes, whole grain products, fortified cereals, or dietary supplements." or "Adequate amounts of folate can be obtained from diets rich in fruits, including citrus fruits and juices, vegetables, including dark green leafy vegetables, legumes, whole grain products, including breads, rice, and pasta, fortified cereals, or a dietary supplement."

(d) *Model health claims.* The following are examples of model health claims that may be used in food labeling to describe the relationship between folate and neural tube defects:

(1) *Examples 1 and 2.* Model health claims appropriate for foods containing 100 percent or less of the DV for folate per serving or per unit (general population). The examples contain only the required elements:

(i) Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

(ii) Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

(2) *Example 3.* Model health claim appropriate for foods containing 100 percent or less of the DV for folate per serving or per unit. The example contains all required elements plus optional information: Women who consume healthful diets with adequate folate throughout their childbearing

years may reduce their risk of having a child with a birth defect of the brain or spinal cord. Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements.

(3) *Example 4.* Model health claim appropriate for foods intended for use by the general population and containing more than 100 percent of the DV of folate per serving or per unit: Women who consume healthful diets with adequate folate may reduce their risk of having a child with birth defects of the brain or spinal cord. Folate intake should not exceed 250% of the DV (1,000 mcg).

[61 FR 8779, Mar. 5, 1996; 61 FR 48529, Sept. 13, 1996, as amended at 65 FR 58918, Oct. 3, 2000]

§ 101.80 Health claims: dietary noncariogenic carbohydrate sweeteners and dental caries.

(a) *Relationship between dietary carbohydrates and dental caries.* (1) Dental caries, or tooth decay, is a disease caused by many factors. Both environmental and genetic factors can affect the development of dental caries. Risk factors include tooth enamel crystal structure and mineral content, plaque quantity and quality, saliva quantity and quality, individual immune response, types and physical characteristics of foods consumed, eating behaviors, presence of acid producing oral bacteria, and cultural influences.

(2) The relationship between consumption of fermentable carbohydrates, i.e., dietary sugars and starches, and tooth decay is well established. Sucrose, also known as sugar, is one of the most, but not the only, cariogenic sugars in the diet. Bacteria found in the mouth are able to metabolize most dietary carbohydrates, producing acid and forming dental plaque. The more frequent and longer the exposure of teeth to dietary sugars and starches, the greater the risk for tooth decay.

(3) Dental caries continues to affect a large proportion of Americans. Although there has been a decline in the prevalence of dental caries among children in the United States, the disease remains widespread throughout the population, imposing a substantial burden on Americans. Recent Federal government dietary guidelines recommend that Americans choose diets that are moderate in sugars and avoid excessive snacking. Frequent between-meal snacks that are high in sugars and starches may be more harmful to teeth than eating such foods at meals and then brushing.

(4) Noncariogenic carbohydrate sweeteners, such as sugar alcohols, can be used to replace dietary sugars, such as sucrose and corn sweeteners, in foods such as chewing gums and certain confectioneries. Noncariogenic carbohydrate sweeteners are significantly less cariogenic than dietary sugars and other fermentable carbohydrates.

(b) *Significance of the relationship between noncariogenic carbohydrate sweeteners and dental caries.* Noncariogenic carbohydrate sweeteners do not promote dental caries. The noncariogenic carbohydrate sweeteners listed in paragraph (c)(2)(ii) of this section are slowly metabolized by bacteria to form some acid. The rate and amount of acid production is significantly less than that from sucrose and other fermentable carbohydrates and does not cause the loss of important minerals from tooth enamel.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met, except that noncariogenic carbohydrate sweetener-containing foods listed in paragraph (c)(2)(ii) of this section are exempt from § 101.14(e)(6).

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim relating noncariogenic carbohydrate sweeteners, compared to other carbohydrates, and the nonpromotion of dental caries may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim shall state that frequent between-meal consumption of foods high in sugars and starches can promote tooth decay.

(B) The claim shall state that the noncariogenic carbohydrate sweetener present in the food "does not promote," "may reduce the risk of," "useful [or is useful] in not promoting," or "expressly [or is expressly] for not promoting" dental caries.

(C) In specifying the nutrient, the claim shall state "sugar alcohol," "sugar alcohols," or the name or names of the substances listed in paragraph (c)(2)(ii) of this section, e.g., "sorbitol." D-tagatose may be identified as "tagatose."

(D) In specifying the disease, the claim uses the following terms: "dental caries" or "tooth decay."

(E) The claim shall not attribute any degree of the reduction in risk of dental caries to the use of the noncariogenic carbohydrate sweetener-containing food.

(F) The claim shall not imply that consuming noncariogenic carbohydrate sweetener-containing foods is the only recognized means of achieving a reduced risk of dental caries.

(G) Packages with less than 15 square inches of surface area available for labeling are exempt from paragraphs (A) and (C) of this section.

(H) When the substance that is the subject of the claim is a noncariogenic sugar, the claim shall identify the substance as a sugar that, unlike other sugars, does not promote the development of dental caries.

(ii) *Nature of the substance.* Eligible noncariogenic carbohydrate sweeteners are:

(A) The sugar alcohols xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, and erythritol, or a combination of these.

(B) The sugars D-tagatose and isomaltulose.

(C) Sucralose.

(iii) *Nature of the food.* (A) The food shall meet the requirement in § 101.60(c)(1)(i) with respect to sugars content, except that the food may contain D-tagatose or isomaltulose.

(B) A food whose labeling includes a health claim under this section shall contain one or more of the noncariogenic carbohydrate sweeteners listed in paragraph (c)(2)(ii) of this section.

(C) When carbohydrates other than those listed in paragraph (c)(2)(ii) of this section are present in the food, the food shall not lower plaque pH below 5.7 by bacterial fermentation either during consumption or up to 30 minutes after consumption, as measured by the indwelling plaque pH test found in "Identification of Low Caries Risk Dietary Components," dated 1983, by T. N. Imfeld, in Volume 11, *Monographs in Oral Science*, 1983. The Director of the Office of the Federal Register has approved the incorporation by reference of this material in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from Karger AG Publishing Co., P.O. Box, Ch–4009 Basel, Switzerland, or you may examine a copy at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which describe the relationship between diets containing noncariogenic carbohydrate sweeteners and dental caries.

(2) The claim may indicate that development of dental caries depends on many factors and may identify one or more of the following risk factors for dental caries: Frequent consumption of fermentable carbohydrates, such as dietary sugars and starches; presence of oral bacteria capable of fermenting carbohydrates; length of time fermentable carbohydrates are in contact with the teeth; lack of exposure to fluoride; individual susceptibility; socioeconomic and cultural factors; and characteristics of tooth enamel, saliva, and plaque.

(3) The claim may indicate that oral hygiene and proper dental care may help to reduce the risk of dental disease.

(4) The claim may indicate that a substance listed in paragraph (c)(2)(ii) of this section serves as a sweetener.

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between noncariogenic carbohydrate sweetener-containing foods and dental caries.

(1) Examples of the full claim:

(i) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. The sugar alcohol [name, optional] used to sweeten this food may reduce the risk of dental caries.

(ii) Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay.

(iii) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. [Name of sugar from paragraph (c)(2)(ii)(B) of this section], the sugar used to sweeten this food, unlike other sugars, may reduce the risk of dental caries.

(iv) Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. [Name of sugar from paragraph (c)(2)(ii)(B) of this section], the sugar in [name of food], unlike other sugars, does not promote tooth decay.

(v) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. Sucralose, the sweetening ingredient used to sweeten this food, unlike sugars, does not promote tooth decay.

(2) Example of the shortened claim for small packages:

(i) Does not promote tooth decay.

(ii) May reduce the risk of tooth decay.

(iii) [Name of sugar from paragraph (c)(2)(ii)(B) of this section] sugar does not promote tooth decay.

(iv) [Name of sugar from paragraph (c)(2)(ii)(B) of this section] sugar may reduce the risk of tooth decay.

[61 FR 43446, Aug. 23, 1996, as amended at 62 FR 63655, Dec. 2, 1997; 66 FR 66742, Dec. 27, 2001; 67 FR 71470, Dec. 2, 2002; 71 FR 15563, Mar. 29, 2006; 72 FR 52789, Sept. 17, 2007; 81 FR 5590, Feb. 3, 2016]

§ 101.81 Health claims: Soluble fiber from certain foods and risk of coronary heart disease (CHD).

(a) *Relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and the risk of CHD.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease (CHD) is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing coronary heart disease. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk total cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of CHD.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL-cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in fiber-containing fruits, vegetables, and grain products, such as whole oat products.

(3) Scientific evidence demonstrates that diets low in saturated fat and cholesterol may reduce the risk of CHD. Other evidence demonstrates that the addition of soluble fiber from certain foods to a diet that is low in saturated fat and cholesterol may also help to reduce the risk of CHD.

(b) *Significance of the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and the risk of CHD.* (1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL-cholesterol are major modifiable risk factors in the development of CHD.

(2) Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One

of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 milligrams (mg) or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total- and LDL-cholesterol levels. Soluble fiber from certain foods, when included in a low saturated fat and cholesterol diet, also helps to lower blood total- and LDL-cholesterol levels.

(c) *Requirements.* (1) All requirements set forth in §101.14 shall be met. The label and labeling of foods containing psyllium husk shall be consistent with the provisions of §101.17(f).

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods "may" or "might" reduce the risk of heart disease.

(B) In specifying the disease, the claim uses the following terms: "heart disease" or "coronary heart disease";

(C) In specifying the substance, the claim uses the term "soluble fiber" qualified by the name of the eligible source of soluble fiber (provided in paragraph (c)(2)(ii)) of this section. Additionally, the claim may use the name of the food product that contains the eligible source of soluble fiber;

(D) In specifying the fat component, the claim uses the terms "saturated fat" and "cholesterol";

(E) The claim does not attribute any degree of risk reduction for CHD to diets that are low in saturated fat and cholesterol and that include soluble fiber from the eligible food sources from paragraph (c)(2)(ii) of this section; and

(F) The claim does not imply that consumption of diets that are low in saturated fat and cholesterol and that include soluble fiber from the eligible food sources from paragraph (c)(2)(ii) of this section is the only recognized means of achieving a reduced risk of CHD.

(G) The claim specifies the daily dietary intake of the soluble fiber source that is necessary to reduce the risk of coronary heart disease and the contribution one serving of the product makes to the specified daily dietary intake level. Daily dietary intake levels of soluble fiber sources listed in paragraph (c)(2)(ii) of this section that have been associated with reduced risk coronary heart disease are:

(*1*) 3 g or more per day of β-glucan soluble fiber from either whole oats or barley, or a combination of whole oats and barley.

(*2*) 7 g or more per day of soluble fiber from psyllium seed husk.

(ii) *Nature of the substance—Eligible sources of soluble fiber.* (A) Beta (β) glucan soluble fiber from the whole oat and barley sources listed below. β-glucan soluble fiber will be determined by method No. 992.28 from the "Official Methods of Analysis of the AOAC INTERNATIONAL," 16th ed. (1995), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*;

(*1*) *Oat bran.* Oat bran is produced by grinding clean oat groats or rolled oats and separating the resulting oat flour by suitable means into fractions such that the oat bran fraction is not more than 50 percent of the original starting material and provides at least 5.5 percent (dry weight basis (dwb)) β-glucan soluble fiber and a total dietary fiber content of 16 percent (dwb), and such that at least one-third of the total dietary fiber is soluble fiber;

(*2*) *Rolled oats.* Rolled oats, also known as oatmeal, produced from 100 percent dehulled, clean oat groats by steaming, cutting, rolling, and flaking, and provides at least 4 percent (dwb) of β-glucan soluble fiber and a total dietary fiber content of at least 10 percent.

(*3*) *Whole oat flour.* Whole oat flour is produced from 100 percent dehulled, clean oat groats by steaming and grinding, such that there is no significant loss of oat bran in the final product, and provides at least 4 percent (dwb) of β-glucan soluble fiber and a total dietary fiber content of at least 10 percent (dwb).

(*4*) *Oatrim.* The soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour, also known as oatrim. Oatrim is produced from either oat bran as defined in paragraph (c)(2)(ii)(A)(*1*) of this section or whole oat flour as defined in paragraph (c)(2)(ii)(A)(*3*) of this section by solubilization of the starch in the starting material with an alpha-amylase hydrolysis process, and then removal by centrifugation of the insoluble components consisting of a high portion of protein, lipid, insoluble dietary fiber, and the majority of the flavor and color components of the starting material. Oatrim shall have a beta-glucan soluble fiber content up to 10 percent (dwb) and not less than that of the starting material (dwb).

(*5*) *Whole grain barley and dry milled barley.* Dehulled and hull-less whole grain barley with a β-glucan soluble fiber content of at least 4 percent (dwb) and a total dietary fiber content of at least 10 percent (dwb). Dry milled barley grain products include barley bran, barley flakes, barley grits, pearl barley, barley flour, barley meal, and sieved barley meal that are produced from clean, sound dehulled or hull-less barley grain using standard dry milling techniques, which may include steaming or tempering, and that contain at least 4 percent (dwb) of β-glucan soluble fiber and at least 8 percent (dwb) of total dietary fiber, except barley bran and sieved barley meal for which the minimum β-glucan soluble fiber content is 5.5 percent (dwb) and minimum total dietary fiber content is 15 percent (dwb). Dehulled barley, hull-less barley, barley bran, barley flakes, barley grits, pearl barley, and barley flour are as defined in the Barley Glossary (AACC Method 55–99), published in Approved Methods of the American Association of Cereal Chemists, 10th ed. (2000), pp. 1 and 2, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Association of Cereal Chemists, Inc., 3340 Pilot Knob Rd., St. Paul, Minnesota, 55121, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Barley meal is unsifted, ground barley grain not subjected to any processing to separate the bran, germ, and endosperm. Sieved barley meal is an endosperm cell wall-enriched fraction of ground barley separated from meal by sieving or by air classification.

(*6*) *Barley betafiber.* Barley betafiber is the ethanol precipitated soluble fraction of cellulase and alpha-amylase hydrolyzed whole grain barley. Barley betafiber is produced by hydrolysis of whole grain barley flour, as defined in paragraph (c)(2)(ii)(A)(*5*) of this section, with a cellulase and alpha-amylase enzyme preparation, to produce a clear aqueous extract that contains mainly partially hydrolyzed beta-glucan and substantially hydrolyzed starch. The soluble, partially hydrolyzed beta-glucan is separated from the insoluble material by centrifugation, and after removal of the insoluble material, the partially hydrolyzed beta-glucan soluble fiber is separated from the other soluble compounds by precipitation with ethanol. The product is then dried, milled and sifted. Barley betafiber shall have a beta-glucan soluble fiber content of at least 70 percent on a dry weight basis.

(B)(*1*) Psyllium husk from the dried seed coat (epidermis) of the seed of *Plantago* (*P.*) ovata, known as blond psyllium or Indian psyllium, *P. indica,*

or *P. psyllium.* To qualify for this claim, psyllium seed husk, also known as psyllium husk, shall have a purity of no less than 95 percent, such that it contains 3 percent or less protein, 4.5 percent or less of light extraneous matter, and 0.5 percent or less of heavy extraneous matter, but in no case may the combined extraneous matter exceed 4.9 percent, as determined by U.S. Pharmacopeia (USP) methods described in USP's "The National Formulary," USP 23, NF 18, p. 1341, (1995), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*;

(*2*) FDA will determine the amount of soluble fiber that is provided by psyllium husk by using a modification of the Association of Official Analytical Chemists' International (AOAC's) method for soluble dietary fiber (991.43) described by Lee et al., "Determination of Soluble and Insoluble Dietary Fiber in Psyllium-containing Cereal Products," *Journal of the AOAC International,* 78 (No. 3):724–729, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*;

(iii) *Nature of the food eligible to bear the claim.* (A) The food product shall include:

(*1*) One or more of the whole oat or barley foods from paragraphs (c)(2)(ii)(A)(*1*), (*2*), (*3*), and (*5*) of this section, and the whole oat or barley foods shall contain at least 0.75 gram (g) of soluble fiber per reference amount customarily consumed of the food product; or

(*2*) The food containing the oatrim from paragraph (c)(2)(ii)(A)(*4*) of this section or the barley betafiber from paragraph (c)(2)(ii)(A)(*6*) of this section shall contain at least 0.75 g of beta-glucan soluble fiber per reference amount customarily consumed of the food product; or

(*3*) Psyllium husk that complies with paragraph (c)(2)(ii)(B) of this section, and the psyllium food shall contain at least 1.7 g of soluble fiber per reference amount customarily consumed of the food product;

(B) The amount of soluble fiber shall be declared in the nutrition label, consistent with § 101.9(c)(6)(i)(A).

(C) The food shall meet the nutrient content requirement in § 101.62 for a "low saturated fat" and "low cholesterol" food; and

(D) The food shall meet the nutrient content requirement in § 101.62(b)(2) for a "low fat" food, unless the food exceeds this requirement due to fat content derived from whole oat sources listed in paragraph (c)(2)(ii)(A) of this section.

(d) *Optional information.* (1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL-cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease;

(2) The claim may state that the relationship between intake of diets that are low in saturated fat and cholesterol and that include soluble fiber from the eligible food sources from paragraph

(c)(2)(ii) of this section and reduced risk of heart disease is through the intermediate link of "blood cholesterol" or "blood total- and LDL-cholesterol;"

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and coronary heart disease and the significance of the relationship;

(4) The claim may specify the name of the eligible soluble fiber;

(5) The claim may state that a diet low in saturated fat and cholesterol that includes soluble fiber from whole oats or barley is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO);

(6) The claim may state that individuals with elevated blood total- and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment;

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, GPO.

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and reduced risk of heart disease:

(1) Soluble fiber from foods such as [name of soluble fiber source from paragraph (c)(2)(ii) of this section and, if desired, the name of food product], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies _____ grams of the [grams of soluble fiber specified in paragraph (c)(2)(i)(G) of this section] soluble fiber from [name of the soluble fiber source from paragraph (c)(2)(ii) of this section] necessary per day to have this effect.

(2) Diets low in saturated fat and cholesterol that include [_____ grams of soluble fiber specified in paragraph (c)(2)(i)(G) of this section] of soluble fiber per day from [name of soluble fiber source from paragraph (c)(2)(ii) of this section and, if desired, the name of the food product] may reduce the risk of heart disease. One serving of [name of food] provides _____ grams of this soluble fiber.

[62 FR 3600, Jan. 23, 1997, as amended at 62 FR 15344, Mar. 31, 1997; 63 FR 8119, Feb. 18, 1998; 66 FR 66742, Dec. 27, 2001; 67 FR 61782, Oct. 2, 2002; 68 FR 15355, Mar. 31, 2003; 70 FR 40880, July 15, 2005; 70 FR 76162, Dec. 23, 2005; 73 FR 9947, Feb. 25, 2008; 73 FR 23953, May 1, 2008; 81 FR 5590, Feb. 3, 2016]

§ 101.82 Health claims: Soy protein and risk of coronary heart disease (CHD).

(a) *Relationship between diets that are low in saturated fat and cholesterol and that include soy protein and the risk of CHD.* (1) Cardiovascular disease means diseases of the heart and circulatory system. CHD is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing CHD. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 millimole per liter (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk total cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total and LDL-cholesterol and, thus, with increased risk of CHD.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL-cholesterol levels. These populations also

tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in plant foods that contain dietary fiber and other components.

(3) Scientific evidence demonstrates that diets low in saturated fat and cholesterol may reduce the risk of CHD. Other evidence demonstrates that the addition of soy protein to a diet that is low in saturated fat and cholesterol may also help to reduce the risk of CHD.

(b) *Significance of the relationship between diets that are low in saturated fat and cholesterol and that include soy protein and the risk of CHD.* (1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL-cholesterol are major modifiable risk factors in the development of CHD.

(2) Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total and LDL-cholesterol levels. Soy protein, when included in a low saturated fat and cholesterol diet, also helps to lower blood total and LDL-cholesterol levels.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets that are low in saturated fat and cholesterol and that include soy protein with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that diets that are low in saturated fat and cholesterol and that include soy protein "may" or "might" reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the following terms: "heart disease" or "coronary heart disease";

(C) In specifying the substance, the claim uses the term "soy protein";

(D) In specifying the fat component, the claim uses the terms "saturated fat" and "cholesterol";

(E) The claim does not attribute any degree of risk reduction for CHD to diets that are low in saturated fat and cholesterol and that include soy protein;

(F) The claim does not imply that consumption of diets that are low in saturated fat and cholesterol and that include soy protein is the only recognized means of achieving a reduced risk of CHD; and

(G) The claim specifies the daily dietary intake of soy protein that is necessary to reduce the risk of coronary heart disease and the contribution one serving of the product makes to the specified daily dietary intake level. The daily dietary intake level of soy protein that has been associated with reduced risk of coronary heart disease is 25 grams (g) or more per day of soy protein.

(ii) *Nature of the substance.* (A) Soy protein from the legume seed Glycine max.

(B) FDA will assess qualifying levels of soy protein in the following fashion: FDA will measure total protein content by the appropriate method of analysis given in the "Official Methods of Analysis of the AOAC International," as described at § 101.9(c)(7). For products that contain no sources of protein other than soy, FDA will consider the amount of soy protein as equivalent to the total protein content. For products that contain a source or sources of protein in addition to soy, FDA will, using the measurement of total protein content, calculate the soy protein content based on the ratio of soy protein ingredients to total protein ingredients in the product. FDA will base its calculation on information identified and supplied by manufacturers, such as nutrient data bases or analyses, recipes or formulations, purchase orders for ingredients, or any

other information that reasonably substantiates the ratio of soy protein to total protein. Manufacturers must maintain records sufficient to substantiate the claim for as long as the products are marketed and provide these records, on written request, to appropriate regulatory officials.

(iii) *Nature of the food eligible to bear the claim.* (A) The food product shall contain at least 6.25 g of soy protein per reference amount customarily consumed of the food product;

(B) The food shall meet the nutrient content requirements in §101.62 for a "low saturated fat" and "low cholesterol" food; and

(C) The food shall meet the nutrient content requirement in §101.62 for a "low fat" food, unless it consists of or is derived from whole soybeans and contains no fat in addition to the fat inherently present in the whole soybeans it contains or from which it is derived.

(d) *Optional information.* (1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL-cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease;

(2) The claim may state that the relationship between intake of diets that are low in saturated fat and cholesterol and that include soy protein and reduced risk of heart disease is through the intermediate link of "blood cholesterol" or "blood total and LDL-cholesterol";

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets that are low in saturated fat and cholesterol and that include soy protein and CHD and the significance of the relationship;

(4) The claim may state that a diet low in saturated fat and cholesterol that includes soy protein is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO);

(5) The claim may state that individuals with elevated blood total and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment;

(6) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, GPO;

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between diets that are low in saturated fat and cholesterol and that include soy protein and reduced risk of heart disease:

(1) 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies ___ grams of soy protein.

(2) Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [name of food] provides ___ grams of soy protein.

[64 FR 57732, Oct. 26, 1999]

EFFECTIVE DATE NOTE: At 64 FR 57732, Oct. 26, 1999, §101.82 was added. Paragraph (c)(2)(ii)(B) of this section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 101.83 Health claims: plant sterol/stanol esters and risk of coronary heart disease (CHD).

(a) *Relationship between diets that include plant sterol/stanol esters and the risk of CHD.* (1) Cardiovascular disease

means diseases of the heart and circulatory system. Coronary heart disease (CHD) is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL) cholesterol levels are associated with increased risk of developing coronary heart disease. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 millimole per liter (mmol/l)) or above and LDL cholesterol levels of 160 mg/dL (4.13 mmol/l) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/l) for total cholesterol, and 130 to 159 mg/dL (3.36 to 4.11 mmol/l) of LDL cholesterol.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in plant foods that contain dietary fiber and other components.

(3) Scientific evidence demonstrates that diets that include plant sterol/stanol esters may reduce the risk of CHD.

(b) *Significance of the relationship between diets that include plant sterol/stanol esters and the risk of CHD.* (1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL cholesterol are major modifiable risk factors in the development of CHD.

(2) The scientific evidence establishes that including plant sterol/stanol esters in the diet helps to lower blood total and LDL cholesterol levels.

(c) *Requirements*—(1) *General.* All requirements set forth in § 101.14 shall be met, except § 101.14(a)(4) with respect to the disqualifying level for total fat per 50 grams (g) in dressings for salad and spreads and § 101.14(e)(6) with respect to dressings for salad.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets that include plant sterol/stanol esters with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that plant sterol/stanol esters should be consumed as part of a diet low in saturated fat and cholesterol;

(B) The claim states that diets that include plant sterol/stanol esters "may" or "might" reduce the risk of heart disease;

(C) In specifying the disease, the claim uses the following terms: "heart disease" or "coronary heart disease";

(D) In specifying the substance, the claim uses the term "plant sterol esters" or "plant stanol esters," except that if the sole source of the plant sterols or stanols is vegetable oil, the claim may use the term "vegetable oil sterol esters" or "vegetable oil stanol esters";

(E) The claim does not attribute any degree of risk reduction for CHD to diets that include plant sterol/stanol esters;

(F) The claim does not imply that consumption of diets that include plant sterol/stanol esters is the only recognized means of achieving a reduced risk of CHD; and

(G) The claim specifies the daily dietary intake of plant sterol or stanol esters that is necessary to reduce the risk of CHD and the contribution one serving of the product makes to the specified daily dietary intake level. Daily dietary intake levels of plant sterol and stanol esters that have been associated with reduced risk of are:

(*1*) 1.3 g or more per day of plant sterol esters.

(*2*) 3.4 g or more per day of plant stanol esters.

(H) The claim specifies that the daily dietary intake of plant sterol or stanol esters should be consumed in two servings eaten at different times of the day with other foods.

(ii) *Nature of the substance*—(A) *Plant sterol esters.* (*1*) Plant sterol esters prepared by esterifying a mixture of plant sterols from edible oils with food-grade fatty acids. The plant sterol mixture shall contain at least 80 percent beta-

sitosterol, campesterol, and stigmasterol (combined weight).

(*2*) FDA will measure plant sterol esters by the method entitled "Determination of the Sterol Content in Margarines, Halvarines, Dressings, Fat Blends and Sterol Fatty Acid Ester Concentrates by Capillary Gas Chromatography," developed by Unilever United States, Inc., dated February 1, 2000. The method, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, may be obtained from the Center for Food Safety and Applied Nutrition, Office of Nutrition, Labeling and Dietary Supplements, Nutrition Programs Staff, 5001 Campus Dr., College Park, MD 20740, and may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796 2030, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(B) *Plant stanol esters.* (*1*) Plant stanol esters prepared by esterifying a mixture of plant stanols derived from edible oils or byproducts of the kraft paper pulping process with food-grade fatty acids. The plant stanol mixture shall contain at least 80 percent sitostanol and campestanol (combined weight).

(*2*) FDA will measure plant stanol esters by the following methods developed by McNeil Consumer Heathcare dated February 15, 2000: "Determination of Stanols and Sterols in Benecol Tub Spread"; "Determination of Stanols and Sterols in Benecol Dressing"; "Determination of Stanols and Sterols in Benecol Snack Bars"; or "Determination of Stanols and Sterols in Benecol Softgels." These methods are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Center for Food Safety and Applied Nutrition, Office of Nutrition, Labeling and Dietary Supplements, Nutrition Programs Staff, 5001 Campus Dr., College Park, MD 20740, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(iii) *Nature of the food eligible to bear the claim.* (A) The food product shall contain:

(*1*) At least 0.65 g of plant sterol esters that comply with paragraph (c)(2)(ii)(A)(*1*) of this section per reference amount customarily consumed of the food products eligible to bear the health claim, specifically spreads and dressings for salad, or

(*2*) At least 1.7 g of plant stanol esters that comply with paragraph (c)(2)(ii)(B)(*1*) of this section per reference amount customarily consumed of the food products eligible to bear the health claim, specifically spreads, dressings for salad, snack bars, and dietary supplements in softgel form.

(B) The food shall meet the nutrient content requirements in §101.62 for a "low saturated fat" and "low cholesterol" food; and

(C) The food must meet the limit for total fat in §101.14(a)(4), except that spreads and dressings for salad are not required to meet the limit for total fat per 50 g if the label of the food bears a disclosure statement that complies with §101.13(h); and

(D) The food must meet the minimum nutrient contribution requirement in §101.14(e)(6) unless it is a dressing for salad.

(d) *Optional information.* (1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease.

(2) The claim may state that the relationship between intake of diets that include plant sterol/stanol esters and reduced risk of heart disease is through the intermediate link of "blood cholesterol" or "blood total and LDL cholesterol."

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets that include plant sterol/stanol esters and the risk of CHD and the significance of the relationship.

(4) The claim may include information from the following paragraph on the relationship between saturated fat and cholesterol in the diet and the risk of CHD: The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total and LDL cholesterol and, thus, with increased risk of CHD. Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total and LDL cholesterol levels.

(5) The claim may state that diets that include plant sterol or stanol esters and are low in saturated fat and cholesterol are consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(6) The claim may state that individuals with elevated blood total and LDL cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total and LDL cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between diets that include plant sterol or stanol esters and reduced risk of heart disease:

(1) *For plant sterol esters:* (i) Foods containing at least 0.65 g per serving of plant sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies _____grams of vegetable oil sterol esters.

(ii) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 1.3 g of vegetable oil sterol esters in two meals may reduce the risk of heart disease. A serving of [name of the food] supplies _____grams of vegetable oil sterol esters.

(2) *For plant stanol esters:* (i) Foods containing at least 1.7 g per serving of plant stanol esters, eaten twice a day with meals for a total daily intake of at least 3.4 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies _____grams of plant stanol esters.

(ii) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 g of vegetable oil stanol esters in two meals may reduce the risk of heart disease. A serving of [name of the food] supplies _____grams of vegetable oil stanol esters.

[65 FR 54717, Sept. 8, 2000; 65 FR 70466, Nov. 24, 2000, as amended at 66 FR 66742, Dec. 27, 2001; 68 FR 15355, Mar. 31, 2003; 70 FR 41958, July 21, 2005]

Subpart F—Specific Requirements for Descriptive Claims That Are Neither Nutrient Content Claims nor Health Claims

§ 101.91 Gluten-free labeling of food.

(a) *Definitions.* (1) The term "gluten-containing grain" means any one of the following grains or their crossbred hybrids (e.g., triticale, which is a cross between wheat and rye):

(i) Wheat, including any species belonging to the genus *Triticum;*

(ii) Rye, including any species belonging to the genus *Secale;* or

(iii) Barley, including any species belonging to the genus *Hordeum.*

(2) The term "gluten" means the proteins that naturally occur in a gluten-containing grain and that may cause adverse health effects in persons with celiac disease (e.g., prolamins and glutelins).

(3) The labeling claim "gluten-free" means:

(i) That the food bearing the claim in its labeling:

(A) Does not contain any one of the following:

(*1*) An ingredient that is a gluten-containing grain (e.g., spelt wheat);

(*2*) An ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten (e.g., wheat flour); or

(*3*) An ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food (i.e., 20 milligrams (mg) or more gluten per kilogram (kg) of food); or

(B) Inherently does not contain gluten; and

(ii) Any unavoidable presence of gluten in the food bearing the claim in its labeling is below 20 ppm gluten (i.e., below 20 mg gluten per kg of food).

(b) *Requirements.* (1) A food that bears the claim "gluten-free" in its labeling and fails to meet the requirements of paragraph (a)(3) of this section will be deemed misbranded.

(2) A food that bears the claim "no gluten," "free of gluten," or "without gluten" in its labeling and fails to meet the requirements of paragraph (a)(3) of this section will be deemed misbranded.

(3) A food that bears the term "wheat" in the ingredient list or in a separate "Contains wheat" statement in its labeling, as required by 21 U.S.C. 343(w)(1)(A), and also bears the claim "gluten-free" or a claim identified in paragraph (b)(2) of this section will be deemed misbranded unless the word "wheat" in the ingredient list or in the "Contains wheat" statement is followed immediately by an asterisk (or other symbol) that refers to another asterisk (or other symbol) in close proximity to the ingredient statement that immediately precedes the following: "The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods."

(c) *Compliance.* When compliance with paragraph (b) of this section is based on an analysis of the food, FDA will use a scientifically valid method that can reliably detect the presence of 20 ppm gluten in a variety of food matrices, including both raw and cooked or baked products.

(d) *Preemption.* A State or political subdivision of a State may not establish or continue into effect any law, rule, regulation, or other requirement that is different from the requirements in this section for the definition and use of the claim "gluten-free," as well as the claims "no gluten," "free of gluten," or "without gluten."

[78 FR 47178, Aug. 5, 2013]

§ 101.93 Certain types of statements for dietary supplements.

(a)(1) No later than 30 days after the first marketing of a dietary supplement that bears one of the statements listed in section 403(r)(6) or the Federal Food, Drug, and Cosmetic Act, the manufacturer, packer, or distributor of the dietary supplement shall notify the Office of Nutritional Products, Labeling and Dietary Supplements (HFS–810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, that it has included such a statement on the label or in the labeling of its product. An original and two copies of this notification shall be submitted.

(2) The notification shall include the following:

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement;

(ii) The text of the statement that is being made;

(iii) The name of the dietary ingredient or supplement that is the subject of the statement, if not provided in the text of the statement; and

(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears.

(3) The notice shall be signed by a responsible individual or the person who can certify the accuracy of the information presented and contained in the notice. The individual shall certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

(b) *Disclaimer.* The requirements in this section apply to the label or labeling of dietary supplements where the dietary supplement bears a statement that is provided for by section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), and the manufacturer, packer, or distributor wishes to take advantage of the exemption to section 201(g)(1)(C) of the act that is provided by compliance with section 403(r)(6) of the act.

(c) *Text for disclaimer.* (1) Where there is one statement, the disclaimer shall be placed in accordance with paragraph (d) of this section and shall state:

> This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(2) Where there is more than one such statement on the label or in the labeling, each statement shall bear the disclaimer in accordance with paragraph (c)(1) of this section, or a plural disclaimer may be placed in accordance with paragraph (d) of this section and shall state:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(d) *Placement.* The disclaimer shall be placed adjacent to the statement with no intervening material or linked to the statement with a symbol (e.g., an asterisk) at the end of each such statement that refers to the same symbol placed adjacent to the disclaimer specified in paragraphs (c)(1) or (c)(2) of this section. On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there such is a statement. The disclaimer shall be set off in a box where it is not adjacent to the statement in question.

(e) *Typesize.* The disclaimer in paragraph (c) of this section shall appear in boldface type in letters of a typesize no smaller than one-sixteenth inch.

(f) *Permitted structure/function statements.* Dietary supplement labels or labeling may, subject to the requirements in paragraphs (a) through (e) of this section, bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease claims under paragraph (g) of this section. If the label or labeling of a product marketed as a dietary supplement bears a disease claim as defined in paragraph (g) of this section, the product will be subject to regulation as a drug unless the claim is an authorized health claim for which the product qualifies.

(g) *Disease claims.* (1) For purposes of 21 U.S.C. 343(r)(6), a "disease" is damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.

(2) FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease (other than a classical nutrient deficiency disease) under 21 U.S.C. 343(r)(6) if it meets one or more of the

criteria listed below. These criteria are not intended to classify as disease claims statements that refer to the ability of a product to maintain healthy structure or function, unless the statement implies disease prevention or treatment. In determining whether a statement is a disease claim under these criteria, FDA will consider the context in which the claim is presented. A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product:

(i) Has an effect on a specific disease or class of diseases;

(ii) Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;

(iii) Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm;

(iv) Has an effect on a disease or diseases through one or more of the following factors:

(A) The name of the product;

(B) A statement about the formulation of the product, including a claim that the product contains an ingredient (other than an ingredient that is an article included in the definition of "dietary supplement" under 21 U.S.C. 321(ff)(3)) that has been regulated by FDA as a drug and is well known to consumers for its use or claimed use in preventing or treating a disease;

(C) Citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims;

(D) Use of the term "disease" or "diseased," except in general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of diseases or to a specific product or ingredient; or

(E) Use of pictures, vignettes, symbols, or other means;

(v) Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;

(vi) Is a substitute for a product that is a therapy for a disease;

(vii) Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases;

(viii) Has a role in the body's response to a disease or to a vector of disease;

(ix) Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or

(x) Otherwise suggests an effect on a disease or diseases.

[62 FR 49886, Sept. 23, 1997, as amended at 62 FR 49867, Sept. 23, 1997; 65 FR 1050, Jan. 6, 2000; 66 FR 17358, Mar. 30, 2001; 66 FR 56035, Nov. 6, 2001]

§ 101.95 "Fresh," "freshly frozen," "fresh frozen," "frozen fresh."

The terms defined in this section may be used on the label or in labeling of a food in conformity with the provisions of this section. The requirements of the section pertain to any use of the subject terms as described in paragraphs (a) and (b) of this section that expressly or implicitly refers to the food on labels or labeling, including use in a brand name and use as a sensory modifier. However, the use of the term "fresh" on labels or labeling is not subject to the requirements of paragraph (a) of this section if the term does not suggest or imply that a food is unprocessed or unpreserved. For example, the term "fresh" used to describe pasteurized whole milk is not subject to paragraph (a) of this section because the term does not imply that the food is unprocessed (consumers commonly understand that milk is nearly always pasteurized). However, the term "fresh" to describe pasta sauce that has been pasteurized or that contains pasteurized ingredients would be subject to paragraph (a) of this section because the term implies that the food is not processed or preserved. Uses of fresh not subject to this regulation will be governed by the provisions of 403(a) of the Federal Food, Drug, and Cosmetic Act (the act).

(a) The term "fresh," when used on the label or in labeling of a food in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation, except as provided in paragraph (c) of this section.

(b) The terms "fresh frozen" and "frozen fresh," when used on the label or in labeling of a food, mean that the food was quickly frozen while still fresh (i.e., the food had been recently harvested when frozen). Blanching of the food before freezing will not preclude use of the term "fresh frozen" to describe the food. "Quickly frozen" means frozen by a freezing system such as blast-freezing (sub-zero Fahrenheit temperature with fast moving air directed at the food) that ensures the food is frozen, even to the center of the food, quickly and that virtually no deterioration has taken place.

(c) *Provisions and restrictions.* (1) The following do not preclude the food from use of the term "fresh:"

(i) The addition of approved waxes or coatings;

(ii) The post-harvest use of approved pesticides;

(iii) The application of a mild chlorine wash or mild acid wash on produce; or

(iv) The treatment of raw foods with ionizing radiation not to exceed the maximum dose of 1 kiloGray in accordance with § 179.26 of this chapter.

(2) A food meeting the definition in paragraph (a) of this section that is refrigerated is not precluded from use of "fresh" as provided by this section.

[58 FR 2426, Jan. 6, 1993]

Subpart G—Exemptions From Food Labeling Requirements

§ 101.100 Food; exemptions from labeling.

(a) The following foods are exempt from compliance with the requirements of section 403(i)(2) of the act (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients).

(1) An assortment of different items of food, when variations in the items that make up different packages packed from such assortment normally occur in good packing practice and when such variations result in variations in the ingredients in different packages, with respect to any ingredient that is not common to all packages. Such exemption, however, shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement (in terms that are as informative as practicable and that are not misleading) indicating by name other ingredients which may be present.

(2) A food having been received in bulk containers at a retail establishment, if displayed to the purchaser with either:

(i) The labeling of the bulk container plainly in view, provided ingredient information appears prominently and conspicuously in lettering of not less than one-fourth of an inch in height; or

(ii) A counter card, sign, or other appropriate device bearing prominently and conspicuously, but in no case with lettering of less than one-fourth of an inch in height, the information required to be stated on the label pursuant to section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the act).

(3) Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of this paragraph (a)(3), incidental additives are:

(i) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.

(ii) Processing aids, which are as follows:

(*a*) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

(*b*) Substances that are added to a food during processing, are converted into constituents normally present in

the food, and do not significantly increase the amount of the constitutents naturally found in the food.

(c) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

(iii) Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

(4) For the purposes of paragraph (a)(3) of this section, any sulfiting agent (sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite, and potassium metabisulfite) that has been added to any food or to any ingredient in any food and that has no technical effect in that food will be considered to be present in an insignificant amount only if no detectable amount of the agent is present in the finished food. A detectable amount of sulfiting agent is 10 parts per million or more of the sulfite in the finished food. Compliance with this paragraph will be determined using sections 20.123–20.125, "Total Sulfurous Acid," in "Official Methods of Analysis of the Association of Official Analytical Chemists," 14th Ed. (1984), which is incorporated by reference and the refinements of the "Total Sulfurous Acid" procedure in the "Monier-Williams Procedure (with Modifications) for Sulfites in Foods," which is appendix A to part 101. A copy of sections 20.123–20–125 of the Official Methods of Analysis of the Association of Official Analytical Chemists" is available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(b) A food repackaged in a retail establishment is exempt from the following provisions of the act if the conditions specified are met.

(1) Section 403(e)(1) of the act (requiring a statement on the label of the name and place of business of the manufacturer, packer, or distributor).

(2) Section 403(g)(2) of the act (requiring the label of a food which purports to be or is represented as one for which a definition and standard of identity has been prescribed to bear the name of the food specified in the definition and standard and, insofar as may be required by the regulation establishing the standard the common names of the optional ingredients present in the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required by these provisions.

(3) Section 403(i)(1) of the act (requiring the label to bear the common or usual name of the food), if the food is displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the common or usual name of the food, or if the common or usual name of the food is clearly revealed by its appearance.

(c) An open container (a container of rigid or semirigid construction, which is not closed by lid, wrapper, or otherwise other than by an uncolored transparent wrapper which does not obscure the contents) of a fresh fruit or fresh vegetable, the quantity of contents of which is not more than 1 dry quart, shall be exempt from the labeling requirements of sections 403(e), (g)(2) (with respect to the name of the food specified in the definition and standard), and (i)(1) of the act; but such exemption shall be on the condition that if two or more such containers are enclosed in a crate or other shipping package, such crate or package shall bear labeling showing the number of such containers enclosed therein and the quantity of the contents of each.

(d) Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in

substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (k), and (q) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will ensure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such food from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(3) The article is an egg product subject to a standard of identity promulgated in part 160 of this chapter, is to be shipped under the conditions specified in paragraph (d) (1) or (2) of this section and for the purpose of pasteurization or other treatment as required in such standard, and each container of such egg product bears a conspicuous tag or label reading "Caution—This egg product has not been pasteurized or otherwise treated to destroy viable Salmonella microorganisms". In addition to safe and suitable bactericidal processes designed specifically for Salmonella destruction in egg products, the term "other treatment" in the first sentence of this paragraph shall include use in acidic dressings in the processing of which the pH is not above 4.1 and the acidity of the aqueous phase, expressed as acetic acid, is not less than 1.4 percent, subject also to the conditions that:

(i) The agreement required in paragraph (d)(2) of this section shall also state that the operator agrees to utilize such unpasteurized egg products in the processing of acidic dressings according to the specifications for pH and acidity set forth in this paragraph, agrees not to deliver the acidic dressing to a user until at least 72 hours after such egg product is incorporated in such acidic dressing, and agrees to maintain for inspection adequate records covering such processing for 2 years after such processing.

(ii) In addition to the caution statement referred to above, the container of such egg product shall also bear the statement "Unpasteurized _____ for use in acidic dressings only", the blank being filled in with the applicable name of the eggs or egg product.

(e) Conditions affecting expiration of exemptions:

(1) An exemption of a shipment or other delivery of a food under paragraph (d) (1) or (3) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(2) An exemption of a shipment or other delivery of a food under paragraph (d) (2) or (3) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by paragraph (d) (2) or (3) of this section.

(3) An exemption of a shipment or other delivery of a food under paragraph (d) (2) or (3) of this section shall expire:

(i) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food constituting such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(ii) Upon refusal by the operator of the establishment where such food is to

be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such paragraph.

(f) The word "processed" as used in this paragraph shall include the holding of cheese in a suitable warehouse at a temperature of not less than 35 °F for the purpose of aging or curing to bring the cheese into compliance with requirements of an applicable definition and standard of identity. The exemptions provided for in paragraph (d) of this section shall apply to cheese which is, in accordance with the practice of the trade, shipped to a warehouse for aging or curing, on condition that the cheese is identified in the manner set forth in one of the applicable following paragraphs, and in such case the provisions of paragraph (e) of this section shall also apply:

(1) In the case of varieties of cheese for which definitions and standards of identity require a period of aging whether or not they are made from pasteurized milk, each such cheese shall bear on the cheese a legible mark showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each cheese, on its wrapper or immediate container, shall be affixed a removable tag bearing the statement "Uncured _____ cheese for completion of curing and proper labeling", the blank being filled in with the applicable name of the variety of cheese. In the case of swiss cheese, the date at which the preliminary manufacturing process had been completed and at which date curing commences is the date on which the shaped curd is removed from immersion in saturated salt solution as provided in the definition and standard of identity for swiss cheese, and such cheese shall bear a removable tag reading, "To be cured and labeled as 'swiss cheese,' but if eyes do not form, to be labeled as 'swiss cheese for manufacturing' ".

(2) In the case of varieties of cheeses which when made from unpasteurized milk are required to be aged for not less than 60 days, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading, "_____ cheese made from unpasteurized milk. For completion of curing and proper labeling", the blank being filled in with the applicable name of the variety of cheese.

(3) In the case of cheddar cheese, washed curd cheese, colby cheese, granular cheese, and brick cheese made from unpasteurized milk, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading "_____ cheese made from unpasteurized milk. For completion of curing and proper labeling, or for labeling as _____ cheese for manufacturing", the blank being filled in with the applicable name of the variety of cheese.

(g) The label declaration of a harmless marker used to identify a particular manufacturer's product may result in unfair competition through revealing a trade secret. Exemption from the label declaration of such a marker is granted, therefore, provided that the following conditions are met:

(1) The person desiring to use the marker without label declaration of its presence has submitted to the Commissioner of Food and Drugs full information concerning the proposed usage and the reasons why he believes label declaration of the marker should be subject to this exemption; and

(2) The person requesting the exemption has received from the Commissioner of Food and Drugs a finding that the marker is harmless and that the exemption has been granted.

(h) Wrapped fish fillets of nonuniform weight intended to be unpacked and marked with the correct weight at or before the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirement of section 403(e)(2) of the act during introduction and movement in interstate commerce and while held for sale prior to weighing and marking:

(1) *Provided,* That (i) The outside container bears a label declaration of the total net weight; and

(ii) The individual packages bear a conspicuous statement "To be weighed at or before time of sale" and a correct statement setting forth the weight of the wrapper;

(2) *Provided further,* That it is the practice of the retail establishment to weigh and mark the individual packages with a correct net-weight statement prior to or at the point of retail sale. A statement of the weight of the wrapper shall be set forth so as to be readily read and understood, using such term as "wrapper tare—ounce", the blank being filled in with the correct average weight of the wrapper used.

(3) The act of delivering the wrapped fish fillets during the retail sale without the correct net-weight statement shall be deemed an act which results in the product's being misbranded while held for sale. Nothing in this paragraph shall be construed as requiring net-weight statements for wrapped fish fillets delivered into institutional trade provided the outside container bears the required information.

(i) Wrapped clusters (consumer units) of bananas of nonuniform weight intended to be unpacked from a master carton or container and weighed at or before the point of retail sale in an establishment other than that where originally packed shall be exempt from the requirements of section 403(e)(2) of the act during introduction and movement in interstate commerce and while held for sale prior to weighing:

(1) *Provided,* That (i) The master carton or container bears a label declaration of the total net weight; and

(ii) The individual packages bear a conspicuous statement "To be weighed at or before the time of sale" and a correct statement setting forth the weight of the wrapper; using such term as "wrapper tare __ ounce", the blank being filled in with the correct average weight of the wrapper used;

(2) *Provided further,* That it is the practice of the retail establishment to weigh the individual packages either prior to or at the time of retail sale.

(3) The act of delivering the wrapped clusters (consumer units) during the retail sale without an accurate net weight statement or alternatively without weighing at the time of sale shall be deemed an act which results in the product's being misbranded while held for sale. Nothing in this paragraph shall be construed as requiring net-weight statements for clusters (consumer units) delivered into institutional trade, provided that the master container or carton bears the required information.

[42 FR 14308, Mar. 15, 1977, as amended at 51 FR 25017, July 9, 1986; 58 FR 2188, 2876, Jan. 6, 1993; 66 FR 17358, Mar. 30, 2001]

§ 101.108 Temporary exemptions for purposes of conducting authorized food labeling experiments.

(a) The food industry is encouraged to experiment voluntarily, under controlled conditions and in collaboration with the Food and Drug Administration, with and other formats for presenting nutrition and other related food labeling information that is consistent with the current quantitative system in §§ 101.9 and 105.66 of this chapter.

(b) Any firm that intends to undertake a labeling experiment that requires exemptions from certain requirements of §§ 101.9 and 105.66 of this chapter should submit a written proposal containing a thorough discussion of each of the following information items that apply to the particular experiment:

(1) A description of the labeling format to be tested;

(2) A statement of the criteria to be used in the experiment for assigning foods to categories, e.g., nutrient or other values defining "low" and "reduced";

(3) A draft of the material to be used in the store, e.g., shelf tags, booklets, posters, etc.;

(4) The dates on which the experiment will begin and end and on which a written report of analysis of the experimental data will be submitted to FDA, together with a commitment not to continue the experiment beyond the proposed ending date without FDA approval;

(5) The geographic area or areas in which the experiment is to be conducted;

(6) The mechanism to measure the effectiveness of the experiment;

(7) The method for conveying to consumers the required nutrition and other labeling information that is exempted from the label during the experiment;

(8) The method that will be or has been used to determine the actual nutritional characteristics of foods for which a claim is made; and

(9) A statement of the sections of the regulations for which an exemption is sought.

(c) The written proposal should be sent to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The proposal should be clearly identified as a request for a temporary exemption for purposes of conducting authorized food labeling experiments and submitted as a citizen petition under §10.30 of this chapter.

(d) Approval for food labeling experiments will be given by FDA in writing. Foods labeled in violation of existing regulations will be subject to regulatory action unless an FDA-approved exemption to the specific regulation has been granted for that specific product.

(e) Reporting requirements contained in §101.108(b) have been approved by this Office of Management and Budget and assigned number 0910–0151.

[48 FR 15240, Apr. 8, 1983, as amended at 59 FR 14364, Mar. 28, 1994; 62 FR 15343, Mar. 31, 1997]

APPENDIX A TO PART 101—MONIER-WILLIAMS PROCEDURE (WITH MODIFICATIONS) FOR SULFITES IN FOOD, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION (NOVEMBER 1985)

The AOAC official method for sulfites (*Official Methods of Analysis*, 14th Edition, 20.123–20.125, AOAC INTERNATIONAL) has been modified, in FDA laboratories, to facilitate the determination of sulfites at or near 10 ppm in food. Method instructions, including modifications, are described below.

Apparatus—The apparatus shown diagrammatically (Figure 1) is designed to accomplish the selective transfer of sulfur dioxide from the sample in boiling aqueous hydrochloric acid to a solution of 3% hydrogen peroxide. This apparatus is easier to assemble than the official apparatus and the back pressure inside the apparatus is limited to the unavoidable pressure due to the height of the 3% H_2O_2 solution above the tip of the bubbler (F). Keeping the backpressure as low as possible reduces the likelihood that sulfur dioxide will be lost through leaks.

The apparatus should be assembled as shown in Fig. 1 with a thin film of stopcock grease on the sealing surfaces of all the joints except the joint between the separatory funnel and the flask. Each joint should be clamped together to ensure a complete seal throughout the analysis. The separatory funnel, B, should have a capacity of 100 ml or greater. An inlet adapter, A, with a hose connector (Kontes K–183000 or equivalent) is required to provide a means of applying a head of pressure above the solution. (A pressure equalizing dropping funnel is not recommended because condensate, perhaps with sulfur dioxide, is deposited in the funnel and the side arm.) The round bottom flask, C, is a 1000 ml flask with three 24/40 tapered joints. The gas inlet tube, D, (Kontes K–179000 or equivalent) should be of sufficient length to permit introduction of the nitrogen within 2.5 cm of the bottom of the flask. The Allihn condenser, E, (Kontes K–431000–2430 or equivalent) has a jacket length of 300 mm. The bubbler, F, was fabricated from glass according to the dimensions given in Fig. 2. The 3% hydrogen peroxide solution can be contained in a vessel, G, with an i.d. of *ca.* 2.5 cm and a depth of 18 cm.

Buret—A 10 ml buret (Fisher Cat. No. 03–848–2A or equivalent) with overflow tube and hose connections for an Ascarite tube or equivalent air scrubbing apparatus. This will permit the maintenance of a carbon dioxide-free atmosphere over the standardized 0.01*N* sodium hydroxide.

Chilled Water Circulator—The condensor must be chilled with a coolant, such as 20% methanol-water, maintained at 5 °C. A circulating pump equivalent to the Neslab Cooiflow 33 is suitable.

Reagents

(a) *Aqueous hydrochloric acid, 4N.*—For each analysis prepare 90 ml of hydrochloric acid by adding 30 ml of concentrated hydrochloric acid (12N) to 60 ml of distilled water.

(b) *Methyl red indicator*—Dissolve 250 mg of methyl red in 100 ml ethanol.

(c) *Hydrogen peroxide solution, 3%*—Dilute ACS reagent grade 30% hydrogen peroxide to 3% with distilled water. Just prior to use, add three drops of methyl red indicator and titrate to a yellow end-point using 0.01*N* sodium hydroxide. If the end-point is exceeded discard the solution and prepare another 3% H_2O_2 solution.

(d) *Standardized titrant, 0.01N NaOH*—Certified reagent may be used (Fisher SO–5–284). It should be standardized with reference standard potassium hydrogen phthalate.

(e) *Nitrogen*—A source of high purity nitrogen is required with a flow regulator that will maintain a flow of 200 cc per minute. To guard against the presence of oxygen in the nitrogen, an oxygen scrubbing solution such as an alkaline pyrogallol trap may be used. Prepare pyrogallol trap as follows:

1. Add 4.5 g pyrogallol to the trap.
2. Purge trap with nitrogen for 2 to 3 minutes.
3. Prepare a KOH solution prepared by adding 65g KOH to 85 ml distilled water (caution: heat).
4. Add the KOH solution to the trap while maintaining an atmosphere of nitrogen in the trap.

Determination

Assemble the apparatus as shown in Fig. 1. The flask C must be positioned in a heating mantle that is controlled by a power regulating device such as Variac or equivalent. Add 400 ml of distilled water to flask C. Close the stopcock of separatory funnel, B, and add 90 ml of 4*N* hydrochloric acid to the separatory funnel. Begin the flow of nitrogen at a rate of 200±10 cc/min. The condenser coolant flow must be initiated at this time. Add 30 ml of 3% hydrogen peroxide, which has been titrated to a yellow end-point with 0.01*N* NaOH, to container G. After fifteen minutes the apparatus and the distilled water will be thoroughly de-oxygenated and the apparatus is ready for sample introduction.

Sample preparation (solids)—Transfer 50 g of food, or a quantity of food with a convenient quantity of SO_2 (500 to 1500 mcg SO_2), to a food processor or blender. Add 100 ml of 5% ethanol in water and briefly grind the mixture. Grinding or blending should be continued only until the food is chopped into pieces small enough to pass through the 24/40 point of flask C.

Sample preparation (liquids)—Mix 50 g of the sample, or a quantity with a convenient quantity of SO_2 (500 to 1500 mcg SO_2), with 100 ml of 5% ethanol in water.

Sample introduction and distillation—Remove the separatory funnel B, and quantitatively transfer the food sample in aqueous ethanol to flask C. Wipe the tapered joint clean with a laboratory tissue, apply stopcock grease to the outer joint of the separatory funnel, and return the separatory funnel, B, to tapered joint flask C. The nitrogen flow through the 3% hydrogen peroxide solution should resume as soon as the funnel, B, is re-inserted into the appropriate joint in flask C. Examine each joint to ensure that it is sealed.

Apply a head pressure above the hydrochloric acid solution in B with a rubber bulb equipped with a valve. Open the stopcock in B and permit the hydrochloric acid solution to flow into flask C. Continue to maintain sufficient pressure above the acid solution to force the solution into the flask C. The stopcock may be closed, if necessary, to pump up the pressure above the acid and then opened again. Close the stopcock before the last few milliliters drain out of the separatory funnel, B, to guard against the escape of sulfur dioxide into the separatory funnel.

Apply the power to the heating mantle. Use a power setting which will cause 80 to 90 drops per minute of condensate to return to the flask from condenser, E. After 1.75 hours of boiling the contents of the 1000 ml flask and remove trap G.

Titration.—Titrate the contents with 0.01*N* sodium hydroxide. Titrate with 0.01*N* NaOH to a yellow end-point that persists for at least twenty seconds. Compute the sulfite content, expressed as micrograms sulfur dioxide per gram of food (ppm) as follows:

$$ppm = (32.03 \times V_B \times N \times 1000) \div Wt$$

where 32.03 = milliequivalent weight of sulfur dioxide; V_B = volume of sodium hydroxide titrant of normality, N, required to reach endpoint; the factor, 1000, converts milliequivalents to microequivalents and Wt = weight (g) of food sample introduced into the 1000 ml flask.

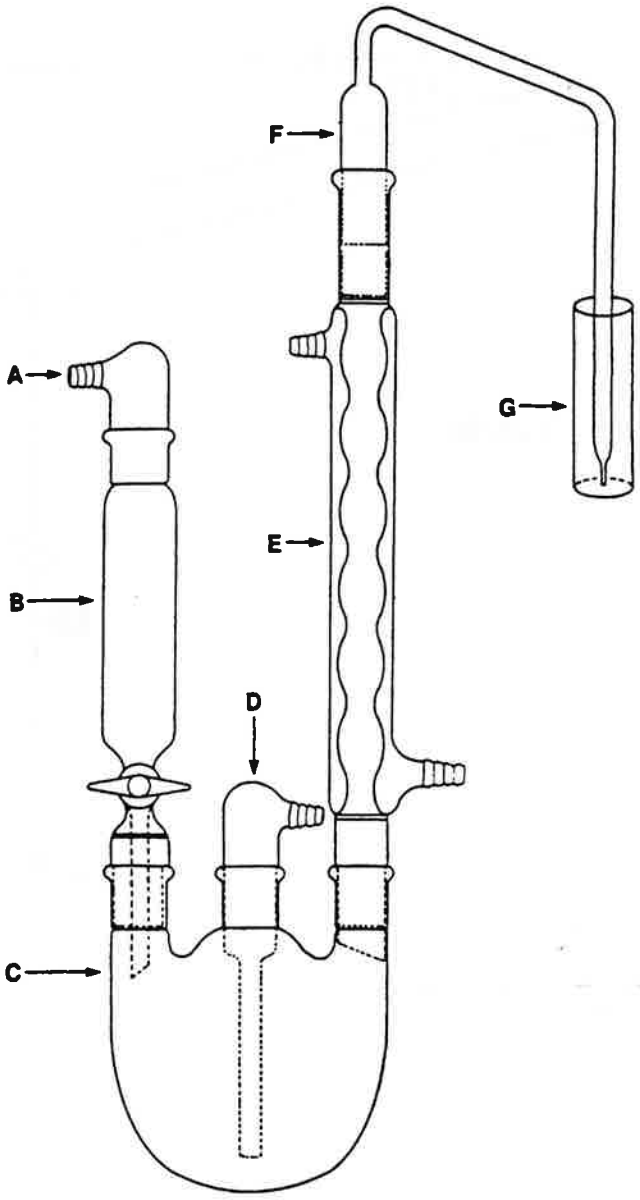


FIGURE 1. THE OPTIMIZED MONIER-WILLIAMS APPARATUS. COMPONENT IDENTIFICATION IS GIVEN IN TEXT.

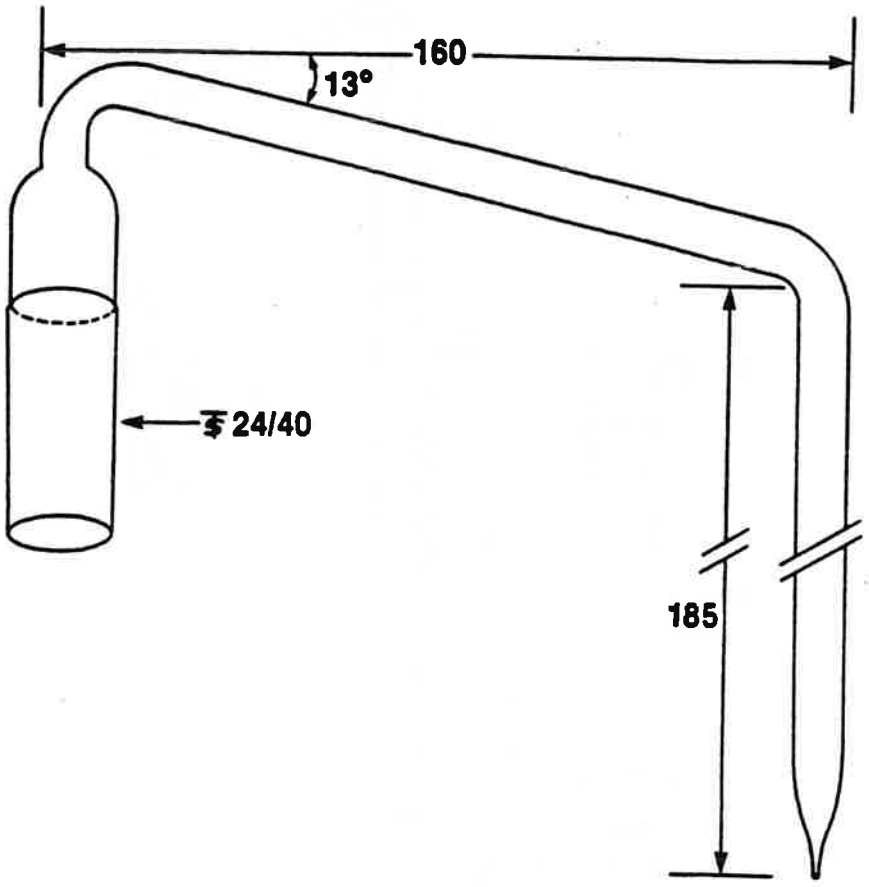


FIGURE 2. DIAGRAM OF BUBBLER (F IN FIGURE 1). LENGTHS ARE GIVEN IN MM.

[42 FR 14308, Mar. 15, 1977, as amended at 51 FR 25017, July 9, 1986]

APPENDIX B TO PART 101—GRAPHIC ENHANCEMENTS USED BY THE FDA

Examples of Graphic Enhancements used by the FDA

A. Overall

1. The Nutrition Facts label is boxed and contains all black or one color type printed on a white or neutral background.

B. Typeface and size

1. The "Nutrition Facts" label uses 6 point or larger Helvetica Black and/or Helvetica Regular type. In order to fit some formats, the typography may be kerned as much as -4 (tighter kerning reduces legibility).

2. Key nutrients and their % Daily Values are set in 8 point Helvetica Black. The "%" symbol also may be set in Helvetica Black.

3. "Nutrition Facts" is set in either Franklin Gothic Heavy or Helvetica Black to fit the width of the label flush left and flush right.

4. "Servings per container" is set in 10 point Helvetica Regular and "Serving size" is set in 10 point Helvetica Black and with 1 point of leading. "Amount per serving" is set in 6 point Helvetica Black.

5. "Calories" is set in 16 point Helvetica Black and the numerical value of calories is set in 22 point Helvetica Black.

6. Absolute measures of nutrient content (for example, "1g") and nutrient subgroups are set in 8 point Helvetica Regular with 4 points of leading.

7. Vitamins and minerals are set in 8 point Helvetica Regular, with 4 points of leading, separated by 8 point bullets.

8. The type for the footnote is set in 6 point Helvetica Regular with 1 point of leading.

C. Rules

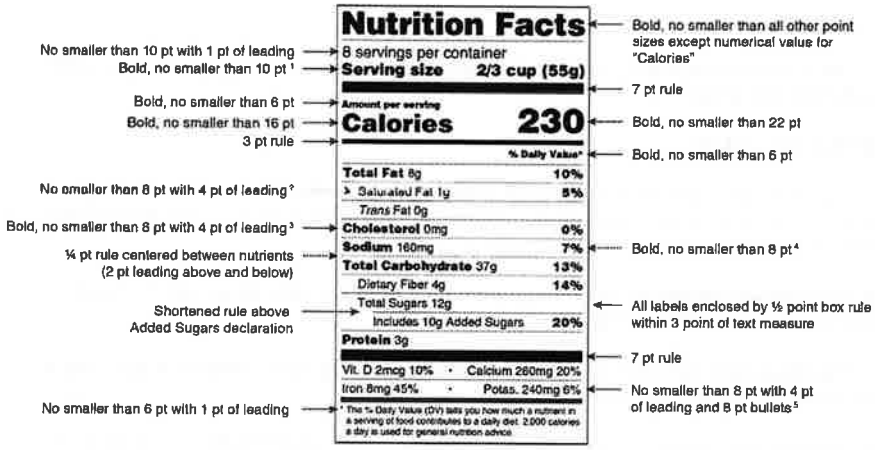
1. A 7 point rule separates large groupings as shown in the example. A 3 point rule separates calorie information from the nutrient information.

2. A hairline rule or ¼ point rule separates individual nutrients, as shown in the example. Descenders do not touch rule. The top half of the label (nutrient information) has 2 points of leading between the type and the rules and the bottom half of the label (footnote) has 1 point of leading between the type and the rules. The rule above the "Added Sugars" declaration is shortened as shown in the example.

D. Box

1. All labels are enclosed by ½ point box rule within 3 points of text measure.

Examples of Graphic Enhancements used by the FDA



[1] Text in bold font is Helvetica Black; text not bolded is Helvetica Regular; leading may be "at least" the point size indicated in all instances

[2] "Serving size" declaration may be decreased to no smaller than 8 pt bold if additional space is needed for the declaration

[3] Saturated fat, *Trans* Fat, Dietary Fiber, Total Sugars, Added Sugars, voluntary nutrients (if listed) and their g/mg values: No smaller than 8 pt with 4 pt of leading

[4] Total Fat, Cholesterol, Sodium, Total Carbohydrate, and Protein: Bold, no smaller than 8 pt with 4 pt of leading

[5] % Daily Values for nutrients that appear between 7 point rules: Bold, no smaller than 8 pt.

[6] Vit. D, Calcium, Iron, Potas., voluntary nutrients (if listed) and their mg/mcg values and % Daily Values: No smaller than 8 pt and with 4 pt of leading

[83 FR 65504, Dec. 21, 2018]

APPENDIX C TO PART 101—NUTRITION FACTS FOR RAW FRUITS AND VEGETABLES

Appendix C to Part 101.--Nutrition Facts for Raw Fruits and Vegetables

Nutrition facts[1] for raw fruits and vegetables edible portion	Calories	Calories from fat	Total Fat		Saturated Fat		Trans Fat	Cholesterol		Sodium		Potassium		Total Carbohydrate		Dietary Fiber		Sugars	Protein	Vitamin A	Vitamin C	Calcium	Iron
			(g)	(%)	(g)	(%)	(g)	(mg)	(%)	(mg)	(%)	(mg)	(%)	(g)	(%)	(g)	(%)	(g)	(g)	(%)	(%)	(%)	(%)
Apple, 1 large (242 g/8 oz)	130	0	0	0	0	0	0	0	0	0	0	260	7	34	11	5	20	25	1	2	8	2	2
Avocado, California, 1/5 medium (30 g/1.1 oz)	50	35	4.5	7	0.5	3	0	0	0	0	0	140	4	3	1	1	4	0	1	0	4	0	2
Banana, 1 medium (126 g/4.5 oz)	110	0	0	0	0	0	0	0	0	0	0	450	13	30	10	3	12	19	1	2	15	0	2
Cantaloupe, 1/4 medium (134 g/4.8 oz)	50	0	0	0	0	0	0	0	0	20	1	240	7	12	4	1	4	11	1	120	80	2	2
Grapefruit, 1/2 medium (154 g/5.5 oz)	60	0	0	0	0	0	0	0	0	0	0	160	5	15	5	2	8	11	1	35	100	4	0
Grapes, 3/4 cup (126 g/4.5 oz)	90	0	0	0	0	0	0	0	0	15	1	240	7	23	8	1	4	20	0	0	2	2	0
Honeydew Melon, 1/10 medium melon (134 g/4.8 oz)	50	0	0	0	0	0	0	0	0	30	1	210	6	12	4	1	4	11	1	2	45	2	2
Kiwifruit, 2 medium (148 g/5.3 oz)	90	10	1	2	0	0	0	0	0	0	0	450	13	20	7	4	16	13	1	2	240	4	2
Lemon, 1 medium (58 g/2.1 oz)	15	0	0	0	0	0	0	0	0	0	0	75	2	5	2	2	8	2	0	0	40	2	0
Lime, 1 medium (67 g/2.4 oz)	20	0	0	0	0	0	0	0	0	0	0	75	2	7	2	2	8	0	0	0	35	0	0
Nectarine, 1 medium (140 g/5.0 oz)	60	5	0.5	1	0	0	0	0	0	0	0	250	7	15	5	2	8	11	1	8	15	0	2
Orange, 1 medium (154 g/5.5 oz)	80	0	0	0	0	0	0	0	0	0	0	250	7	19	6	3	12	14	1	2	130	6	0
Peach, 1 medium (147 g/5.3 oz)	60	0	0.5	1	0	0	0	0	0	0	0	230	7	15	5	2	8	13	1	6	15	0	2
Pear, 1 medium (166 g/5.9 oz)	100	0	0	0	0	0	0	0	0	0	0	190	5	26	9	6	24	16	1	0	10	2	0
Pineapple, 2 slices, 3" diameter, 3/4" thick (112 g/4 oz)	50	0	0	0	0	0	0	0	0	10	0	120	3	13	4	1	4	10	1	2	50	2	2
Plums, 2 medium (151 g/5.4 oz)	70	0	0	0	0	0	0	0	0	0	0	230	7	19	6	2	8	16	1	8	10	0	2
Strawberries, 8 medium (147g/5.3 oz)	50	0	0	0	0	0	0	0	0	0	0	170	5	11	4	2	8	8	1	0	160	2	2
Sweet cherries, 21 cherries; 1 cup (140 g/5.0 oz)	100	0	0	0	0	0	0	0	0	0	0	350	10	26	9	1	4	16	1	2	15	2	2
Tangerine, 1 medium (109 g/1.9 oz)	50	0	0	0	0	0	0	0	0	0	0	160	5	13	4	2	8	9	1	6	45	4	0
Watermelon, 1/18 medium melon; 2 cups diced pieces (280 g/10.0 oz)	80	0	0	0	0	0	0	0	0	0	0	270	8	21	7	1	4	20	1	30	25	2	4

Appendix C to Part 101.--Nutrition Facts for Raw Fruits and Vegetables-continued

Nutrition facts[1] for raw fruits and vegetables edible portion	Calories	Calories from fat	Total Fat		Saturated Fat		Trans Fat	Cholesterol		Sodium		Potassium		Total Carbohydrate		Dietary Fiber		Sugars	Protein	Vitamin A	Vitamin C	Calcium	Iron
			(g)	(%)	(g)	(%)	(g)	(mg)	(%)	(mg)	(%)	(mg)	(%)	(g)	(%)	(g)	(%)	(g)	(g)	(%)	(%)	(%)	(%)
Asparagus, 5 spears (93 g/3.3 oz)	20	0	0	0	0	0	0	0	0	0	0	230	7	4	1	2	8	2	2	10	15	2	2
Bell pepper, 1 medium (148 g/5.3 oz)	25	0	0	0	0	0	0	0	0	40	2	220	6	6	2	2	8	4	1	4	190	2	4
Broccoli, 1 medium stalk (148 g/5.3 oz)	45	0	0.5	1	0	0	0	0	0	80	3	460	13	8	3	3	12	2	4	6	220	6	6
Carrot, 1 carrot, 7" long, 1 1/4" diameter (78 g/2.8 oz)	30	0	0	0	0	0	0	0	0	60	3	250	7	7	2	2	8	5	1	110	10	2	2
Cauliflower, 1/6 medium head (99 g/3.5 oz)	25	0	0	0	0	0	0	0	0	30	1	270	8	5	2	2	8	2	2	0	100	2	2
Celery, 2 medium stalks (110 g/3.9 oz)	15	0	0	0	0	0	0	0	0	115	5	260	7	4	1	2	8	2	0	10	15	4	2
Cucumber, 1/3 medium (99 g/3.5 oz)	10	0	0	0	0	0	0	0	0	0	0	140	4	2	1	1	4	1	1	4	10	2	2
Green (snap) beans, 3/4 cup cut (83 g/3.0 oz)	20	0	0	0	0	0	0	0	0	0	0	200	6	5	2	3	12	2	1	4	10	4	2
Green cabbage, 1/12 medium head (84 g/3.0 oz)	25	0	0	0	0	0	0	0	0	20	1	190	5	5	2	2	8	3	1	0	70	4	2
Green onion, 1/4 cup chopped (25 g/0.9 oz)	10	0	0	0	0	0	0	0	0	10	0	70	2	2	1	1	4	1	0	2	8	2	2
Iceberg lettuce, 1/6 medium head (89 g/3.2 oz)	10	0	0	0	0	0	0	0	0	10	0	125	4	2	1	1	4	2	1	6	6	2	2
Leaf lettuce, 1 1/2 cups shredded (85 g/3.0 oz)	15	0	0	0	0	0	0	0	0	35	1	170	5	2	1	1	4	1	1	130	6	2	4
Mushrooms, 5 medium (84 g/3.0 oz)	20	0	0	0	0	0	0	0	0	15	0	300	9	3	1	1	4	0	3	0	2	0	2
Onion, 1 medium (148 g/5.3 oz)	45	0	0	0	0	0	0	0	0	5	0	190	5	11	4	3	12	9	1	0	20	4	4
Potato, 1 medium (148 g/5.3 oz)	110	0	0	0	0	0	0	0	0	0	0	620	18	26	9	2	8	1	3	0	45	2	6
Radishes, 7 radishes (85 g/3.0 oz)	10	0	0	0	0	0	0	0	0	55	2	190	5	3	1	1	4	2	0	0	30	2	2
Summer squash, 1/2 medium (98 g/3.5 oz)	20	0	0	0	0	0	0	0	0	0	0	260	7	4	1	2	8	2	1	6	30	2	2
Sweet corn, kernels from 1 medium ear (90 g/3.2 oz)	90	20	2.5	4	0	0	0	0	0	0	0	250	7	18	6	2	8	5	4	2	10	0	2
Sweet Potato, 1 medium, 5" long, 2"diameter (130 g/4.6 oz)	100	0	0	0	0	0	0	0	0	70	3	440	13	23	8	4	16	7	2	120	30	4	4
Tomato, 1 medium (148 g/5.3 oz)	25	0	0	0	0	0	0	0	0	20	1	340	10	5	2	1	4	3	1	20	40	2	4

[1] Raw, edible weight portion. Percent (%) Daily Values are based on a 2,000 calorie diet.

[71 FR 47439, Aug. 17, 2006]

APPENDIX D TO PART 101—NUTRITION FACTS FOR COOKED FISH

Appendix D to Part 101.--Nutrition Facts for Cooked Fish

Nutrition facts[1] fish (84 g/3 oz)	Calories	Calories from fat	Total Fat		Saturated Fat		Trans Fat	Cholesterol		Sodium		Potassium		Total Carbohydrate		Dietary Fiber		Sugars	Protein	Vitamin A	Vitamin C	Calcium	Iron
			(g)	(%)	(g)	(%)	(g)	(mg)	(%)	(mg)	(%)	(mg)	(%)	(g)	(%)	(g)	(%)	(g)	(g)	(%)	(%)	(%)	(%)
Blue crab	100	10	1	2	0	0	0	95	32	330	14	300	9	0	0	0	0	0	20	0	4	10	4
Catfish	130	60	6	9	2	10	0	50	17	40	2	230	7	0	0	0	0	0	17	0	0	0	0
Clams, about 12 small	110	15	1.5	2	0	0	0	80	27	95	4	470	13	6	2	0	0	0	17	10	0	8	30
Cod	90	5	1	2	0	0	0	50	17	65	3	460	13	0	0	0	0	0	20	0	2	2	2
Flounder/sole	100	15	1.5	2	0	0	0	55	18	100	4	390	11	0	0	0	0	0	19	0	0	2	0
Haddock	100	10	1	2	0	0	0	70	23	85	4	340	10	0	0	0	0	0	21	2	0	2	6
Halibut	120	15	2	3	0	0	0	40	13	60	3	500	14	0	0	0	0	0	23	4	0	2	6
Lobster	80	0	0.5	1	0	0	0	60	20	320	13	300	9	1	0	0	0	0	17	2	0	6	2
Ocean perch	110	20	2	3	0.5	3	0	45	15	95	4	290	8	0	0	0	0	0	21	0	2	10	4
Orange roughy	80	5	1	2	0	0	0	20	7	70	3	340	10	0	0	0	0	0	16	2	0	4	2
Oysters, about 12 medium	100	35	4	6	1	5	0	80	27	300	13	220	6	6	2	0	0	0	10	0	6	6	45
Pollock	90	10	1	2	0	0	0	80	27	110	5	370	11	0	0	0	0	0	20	2	0	0	2
Rainbow trout	140	50	6	9	2	10	0	55	18	35	1	370	11	0	0	0	0	0	20	4	4	8	2
Rockfish	110	15	2	3	0	0	0	40	13	70	3	440	13	0	0	0	0	0	21	4	0	2	2
Salmon, Atlantic/Coho/Sockeye/Chinook	200	90	10	15	2	10	0	70	23	55	2	430	12	0	0	0	0	0	24	4	4	2	2
Salmon, Chum/Pink	130	40	4	6	1	5	0	70	23	65	3	420	12	0	0	0	0	0	22	2	0	2	4
Scallops, about 6 large or 14 small	140	10	1	2	0	0	0	65	22	310	13	430	12	5	2	0	0	0	27	2	0	4	14
Shrimp	100	10	1.5	2	0	0	0	170	57	240	10	220	6	0	0	0	0	0	21	4	4	6	10
Swordfish	120	50	6	9	1.5	8	0	40	13	100	4	310	9	0	0	0	0	0	16	2	2	0	6
Tilapia	110	20	2.5	4	1	5	0	75	25	30	1	360	10	0	0	0	0	0	22	0	2	0	2
Tuna	130	15	1.5	2	0	0	0	50	17	40	2	480	14	0	0	0	0	0	26	2	2	2	4

[1] Cooked, edible weight portion. **Percent (%) Daily Values are based on a 2,000 calorie diet.**

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