

**DEPARTMENT OF AGRICULTURE****Food Safety and Inspection Service****9 CFR Parts 317 and 381**

[Docket No. 94-029F]

**Nutrition Labeling of Meat and Poultry Products; Codification**

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is amending its final nutrition labeling regulations to provide codified language for provisions that previously cross-referenced those requirements contained in the final nutrition labeling regulations of the Food and Drug Administration (FDA) that FSIS adopted. FSIS is taking this action to provide complete codified language for the nutrition labeling of meat and poultry products in the regulations under 9 CFR parts 317 and 381. Full codification of the final FSIS nutrition labeling regulations will facilitate their use by improving their clarity and accessibility.

**EFFECTIVE DATE:** January 3, 1995, except that the amendments to §§ 317.363 and 381.463 are effective on November 10, 1995. The incorporation by reference of Agriculture Handbook No. 74 (Slightly revised February 1973), pages 2, 3, 9-11, and 25, and the "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990, sections 5.4.1, 7.2.1, and 8, contained in these regulations, is approved by the Director of the Office of the Federal Register as of January 3, 1995.

**FOR FURTHER INFORMATION CONTACT:** Charles Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 254-2565.

**SUPPLEMENTARY INFORMATION:****Background**

FSIS published its final nutrition labeling regulations in the **Federal Register** on January 6, 1993 (58 FR 632). Corrections and technical amendments to this final rule were published on August 18, 1993 (58 FR 43787), and September 10, 1993 (58 FR 47624), respectively. The technical amendments, which were issued as an interim final rule, were confirmed as final on March 16, 1994 (59 FR 12157). FSIS also published a final rule on placement of nutrition labeling on meat and poultry products on August 8, 1994

(59 FR 40209), and a final rule with additional technical amendments to the nutrition labeling regulations on September 1, 1994 (59 FR 45189). Most of the changes FSIS made in the final rules pertaining to technical amendments and the placement of nutrition labeling on meat and poultry products were designed to parallel similar changes that FDA made to its nutrition labeling regulations. FSIS adopted certain changes made by FDA in cross-referenced provisions, in addition to amending certain of its own provisions to be consistent with those changes.

The codified portion of FSIS's final regulations published on January 6, 1993, cross-referenced provisions of FDA's regulations where the requirements are identical, and, for the most part, provided codified language only for those provisions where there are variations from FDA because of the different products that FSIS regulates. FSIS used cross-references in order to issue its final nutrition labeling regulations simultaneously with FDA on January 6, 1993. In the preamble to its final rule of January 6, 1993, FSIS said that it had received many comments which suggested that the Agency include all of the codified language for the nutrition labeling of meat and poultry products in the regulations under 9 CFR parts 317 and 381. The commenters stated that it is very difficult to go back and forth between FDA and FSIS regulations to look up different provisions for the nutrition labeling regulations. FSIS agreed with these comments and said it planned to publish the codified language in its entirety, while noting that future codification did not postpone the implementation date of the nutrition labeling regulations.

**The Amendments**

This document sets forth in entirety the codified language for previously cross-referenced nutrition labeling provisions. It includes all changes in the above-mentioned final rules as they apply to the cross-referenced provisions. Sections that contain cross-referenced provisions include those pertaining to the nutrition label content (serving sizes; mandatory and voluntary nutrients; and format requirements for the standard display, dual column display, and simplified format); Reference Amounts Customarily Consumed per eating occasion; general principles for nutrient content claims; nutrient content claims (claims for "good source," "high," and "more"; "light" or "lite"; calorie content; sodium content; and fat, fatty acids, and

cholesterol content); and label statements for reducing or maintaining body weight.

In incorporating the previously cross-referenced provisions contained in 21 CFR, FSIS has made an effort to order the paragraphs and subdivisions, to the extent possible, in the same sequence as the comparable paragraphs and subdivisions in FDA's nutrition labeling regulations in 21 CFR. Accordingly, some existing paragraphs have been redesignated. FSIS believes that such consistency of presentation will be useful to interested parties who compare the FSIS and FDA provisions, and to those manufacturers producing both FSIS- and FDA-regulated products who refer to both agencies' regulations for nutrition labeling requirements.

FSIS is also making several amendments to sections of the nutrition labeling regulations (9 CFR part 317, subpart B, and part 381, subpart Y) that do not contain cross-referenced provisions to correct typographical errors, make minor editorial changes for clarity and accuracy, and reorder information in several paragraphs to improve clarity and readability. For example, in part 317, the terminology for "meat products" is changed, in most cases, to "meat or meat food products," which mirrors the statutory language contained in the Federal Meat Inspection Act. The term "product component" is changed to "food component" when it refers to a constituent of food whose declaration on product labeling is mandatory or voluntary under the regulations, and ingredients with specific food factors for calorie calculations. Cross-references within paragraphs in various sections of the nutrition labeling provisions are changed to conform with any redesignated paragraph that is the subject of the cross-reference. Units of measure and weights are, for the most part, abbreviated after their first appearance within a section.

FSIS provided provisions at 9 CFR 317.309(e)(2)(i) and 381.409(e)(2)(i) for use of an aggregate display of nutrition information on the outer label or labeling of products that contain two or more products in the same package. However, in 9 CFR 317.309(e)(2)(ii) and 381.409(e)(2)(ii) that specify the format requirements for the aggregate display, FSIS inadvertently provided that the identity of each food shall be specified immediately under the "Nutrition Facts" title. In fact, the identity of the food is placed to the right of the "Nutrition Facts" title as illustrated by a sample label for the aggregate display at 21 CFR 101.9(d)(13)(ii). FSIS is correcting this oversight in paragraphs 9

CFR 317.309(e)(2)(ii) and 381.409(e)(2)(ii), which are redesignated as 9 CFR 317.309(d)(13)(ii) and 381.409(d)(13)(ii), respectively.

FSIS is revising the language of 9 CFR 317.309(g) and 381.409(g) to clarify the identity of nutrients that shall be included in a simplified format and those that may be included voluntarily. Sections 317.309(g)(2) and 381.409(g)(2) (9 CFR 317.309(g)(2) and 381.409(g)(2)) specify that the simplified format shall include serving size, number of servings per container, calories, total fat, total carbohydrate, protein, and sodium. The provisions do not provide specifically that calories from fat, saturated fat, cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron also must be declared in the simplified format when any are present in more than insignificant amounts, as must any added vitamins and minerals for which Reference Daily Intakes (RDI) are established if their addition were to be allowed. Those provisions also do not indicate that other nutrients for which nutrition labeling is voluntary (e.g., sugar alcohol or thiamin) may also be declared in the simplified format. FSIS is redesignating sections 317.309(g) and 381.409(g) as 317.309(f) and 381.409(f), respectively, revising the newly designated paragraphs, and adding a paragraph to specify the requirements completely. This action provides codified language that is consistent with comparable FDA provisions at 21 CFR 101.9(f) and prevents misinterpretation of the simplified format provisions.

FSIS is amending 9 CFR 317.313(q)(4) and 381.414(q)(4) pertaining to exemptions from the general principles for nutrient content claims by correcting the terminology for the products that are not subject to the provisions in the sections. Accordingly, the term "products for special dietary use" is changed to read "infant formulas and medical foods," which is the terminology employed by FDA in the comparable provision in 21 CFR at 101.13(q)(4). Products for special dietary use, as described in 21 CFR part 105, include products such as hypoallergenic products, products designed for weight reduction or weight maintenance, products for use in diets of diabetics, and products used to regulate sodium intake, all of which are subject to the provisions of 9 CFR 317.313 and 381.413. To leave the terminology uncorrected creates an apparent conflict with provisions in the sections of the nutrition labeling regulations pertaining to nutrient content claims about calorie content (9 CFR 317.360 and 381.460) and sodium content (9 CFR 313.361 and 381.461), and label or labeling

statements relating to usefulness in reducing or maintaining body weight (9 CFR 317.380 and 381.480).

At 9 CFR 317.345(a)(2) and 381.445(a)(2), FSIS set forth guidelines for voluntary nutrition labeling of single-ingredient, raw products that specify that point-of-purchase materials are not subject to any format requirements if only nutrition information, and not a nutrition claim, is supplied on point-of-purchase materials. FSIS specifically mentioned that listing of Daily Reference Values, which is a footnote, is voluntary but did not specify that the listing of percent of Daily Value is also a format requirement. FSIS is making minor editorial changes in 9 CFR 317.345(a)(2) and 381.445(a)(2) to clarify this point and is reordering some of the information to improve readability.

In addition, at 9 CFR 317.362(f)(1) and 381.462(f)(2), FSIS used the following statements as examples of declarations of quantitative information for claims of cholesterol free, low cholesterol, or reduced cholesterol that compare the level of cholesterol in an individual food product with that of a reference food: (e.g., "contains no cholesterol compared with 30 mg in one serving of 'reference food'; contains 11 g of fat per serving" or "cholesterol lowered from 30 mg to 5 mg per serving; contains 13 g of fat per serving"). FSIS is not including in these amendments those portions of the statements that disclose fat contents, that is, "contains 11 grams of fat per serving" and "contains 13 g of fat per serving," because FSIS does not require such disclosure but, rather, permits disclosure on an optional basis.

#### **Executive Order 12866**

This final rule has been determined to be not significant for purposes of Executive Order 12866 and therefore has not been reviewed by the Office of Management and Budget.

#### **Executive Order 12778**

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirement on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA or PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of

preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and PPIA, States that maintain meat and poultry inspection programs must impose requirements that are at least equal to those required under the FMIA and PPIA. The States may, however, impose more stringent requirements on such State inspected products and establishments.

No retroactive effect will be given to this final rule. The administrative procedures specified in 9 CFR 306.5 and 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this final rule, if the challenge involves any decision of an inspector relating to inspection services provided under the FMIA or PPIA. The administrative procedures specified in 9 CFR parts 335 and 381, subpart W, must be exhausted prior to any judicial challenge of the application of the provisions of this final rule with respect to labeling decisions.

#### **Effect on Small Entities**

The Administrator, FSIS, has made a determination that this final rule will not have a significant economic impact on a substantial number of small entities. This final rule simply codifies into 9 CFR the 21 CFR provisions that were previously cross-referenced in 9 CFR 317 and 381 pertaining to nutrition labeling. In addition, small entities are exempt from nutrition labeling regulations, provided their products do not make nutrition claims or nutrition information.

#### **List of Subjects**

##### *9 CFR Part 317*

Food labeling, Food packaging, Incorporation by reference, Meat inspection.

##### *9 CFR Part 381*

Food labeling, Incorporation by reference, Poultry and poultry products.

#### **Final Rule**

For the reasons discussed in the preamble, FSIS is amending 9 CFR parts 317 and 381 of the Federal meat and poultry products inspection regulations as follows:

#### **PART 317—LABELING, MARKING DEVICES, AND CONTAINERS**

1. The authority citation for part 317 continues to read as follows:

**Authority:** 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Section 317.300 is amended by revising the section heading, paragraph (a) and the first sentence of paragraph (b) to read as follows:

**§ 317.300 Nutrition labeling of meat or meat food products.**

(a) Nutrition labeling shall be provided for all meat or meat food products intended for human consumption and offered for sale, except single-ingredient, raw products, in accordance with the requirements of § 317.309; except as exempted under § 317.400 of this subpart.

(b) Nutrition labeling may be provided for single-ingredient, raw meat or meat food products in accordance with the requirements of §§ 317.309 and 317.345. \* \* \*

3. Section 317.302 is amended by adding the words "or meat food" after the words "packaged meat" in paragraph (a) and after the word "Meat" in the first sentence of paragraph (c).

4. Section 317.308 is amended by adding the words "or meat food" after the word "meat" in the section title and after the word "meat" in the text.

5. Section 317.309 is amended by changing the section reference in the fifth sentence of paragraph (h)(2) from "317.309(b)" to "317.309(c)" and revising paragraphs (a) through (g) to read as follows:

**§ 317.309 Nutrition label content.**

(a) All nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(b)(1) The term "serving" or "serving size" means an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the product. When the product is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

(2) Except as provided in paragraphs (b)(8), (b)(12), and (b)(14) of this section and for products that are intended for weight control and are available only through a weight-control or weight-maintenance program, serving size declared on a product label shall be determined from the "Reference Amounts Customarily Consumed Per Eating Occasion—General Food Supply" (Reference Amount(s)) that appear in § 317.312(b) using the procedures described in this paragraph (b). For products that are both intended for weight control and available only

through a weight-control program, a manufacturer may determine the serving size that is consistent with the meal plan of the program. Such products must bear a statement, "for sale only through the \_\_\_\_\_ program" (fill in the blank with the name of the appropriate weight-control program, e.g., Smith's Weight Control), on the principal display panel. However, the Reference Amounts in § 317.312(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrition claims.

(3) The declaration of nutrient and food component content shall be on the basis of the product "as packaged" for all products, except that single-ingredient, raw products may be declared on the basis of the product "as consumed" as set forth in § 317.345(a)(1). In addition to the required declaration on the basis of "as packaged" for products other than single-ingredient, raw products, the declaration may also be made on the basis of "as consumed," provided that preparation and cooking instructions are clearly stated.

(4) For products in discrete units (e.g., hot dogs, and individually packaged products within a multi-serving package), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., beef fritters and barbecue sauce), the serving size shall be declared as follows:

(i) If a unit weighs 50 percent or less of the Reference Amount, the serving size shall be the number of whole units that most closely approximates the Reference Amount for the product category.

(ii) If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may declare one unit or two units as the serving size.

(iii) If a unit weighs 67 percent or more but less than 200 percent of the Reference Amount, the serving size shall be one unit.

(iv) If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare one unit as the serving size if the whole unit can reasonably be consumed at a single eating occasion.

(v) For products that have Reference Amounts of 100 grams (or milliliter) or larger and are individual units within a multi-serving package, if a unit contains more than 150 percent but less than 200 percent of the Reference Amount, the manufacturer may decide whether to

declare the individual unit as 1 or 2 servings.

(vi) For products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., beef fritters and barbecue sauce), the serving size may be the number of discrete units represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product as determined in § 317.312(c).

(vii) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the serving size shall be 1 unit.

(5) For products in large discrete units that are usually divided for consumption (e.g., pizza), for unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g. pizza kit), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a large discrete unit usually divided for consumption, the serving size shall be the fractional slice of the ready-to-eat product (e.g.,  $\frac{1}{8}$  quiche,  $\frac{1}{4}$  pizza) that most closely approximates the Reference Amount for the product category. The serving size may be the fraction of the package used to make the Reference Amount for the unprepared product determined in § 317.312(d) or the fraction of the large discrete unit represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount of the combined product determined in § 317.312(c). In expressing the fractional slice, manufacturers shall use  $\frac{1}{2}$ ,  $\frac{1}{3}$ ,  $\frac{1}{4}$ ,  $\frac{1}{5}$ ,  $\frac{1}{6}$ , or smaller fractions that can be generated by further division by 2 or 3.

(6) For nondiscrete bulk products (e.g., whole roast beef, marinated beef tenderloin, large can of chili), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a bulk product (e.g., roast beef and gravy), the serving size shall be the amount in household measure that most closely approximates the Reference Amount for the product category and may be the amount of the bulk product represented as the main ingredient plus proportioned minor ingredients used to

make the Reference Amount for the combined product determined in § 317.312(c).

(7) For labeling purposes, the term "common household measure" or "common household unit" means cup, tablespoon, teaspoon, piece, slice, fraction (e.g.,  $\frac{1}{4}$  pizza), ounce (oz), or other common household equipment used to package food products (e.g., jar or tray). In expressing serving size in household measures, except as specified in paragraphs (b)(7)(iv), (v), and (vi) of this section, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate. Cups shall be expressed in  $\frac{1}{4}$ - or  $\frac{1}{3}$ -cup increments, tablespoons in whole number of tablespoons for quantities less than  $\frac{1}{4}$  cup but greater than or equal to 2 tablespoons (tbsp), 1,  $1\frac{1}{3}$ ,  $1\frac{1}{2}$ , or  $1\frac{2}{3}$  tsp for quantities less than 2 tsp but greater than or equal to 1 tsp, and teaspoons in whole number of teaspoons for quantities less than 1 tsp but greater than or equal to 1 teaspoon (tsp), and in  $\frac{1}{4}$ -tsp increments for quantities less than 1 tsp.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5-ounce increments most closely approximating the Reference Amount with rounding indicated by the use of the term "about" (e.g., about 2.5 ounces).

(iv) A description of the individual container or package shall be used for single-serving containers and meal-type products and for individually packaged products within multi-serving containers (e.g., can, box, package, meal, or dinner). A description of the individual unit shall be used for other products in discrete units (e.g., chop, slice, link, or patty).

(v) For unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g., pizza kit), the fraction or portion of the package may be used.

(vi) For products that consist of two or more distinct ingredients or components packaged and presented to be consumed together (e.g., ham with a glaze packet), the nutrition information may be declared for each component or as a composite. The serving size may be provided in accordance with the provisions of paragraphs (b)(4), (b)(5), and (b)(6) of this section.

(vii) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL), a tablespoon means 15 mL, a cup means 240 mL, and 1 oz in weight means 28 grams (g).

(viii) When a serving size, determined from the Reference Amount in § 317.312(b) and the procedures described in this section, falls exactly half way between two serving sizes (e.g., 2.5 tsp), manufacturers shall round the serving size up to the next incremental size.

(8) A product that is packaged and sold individually and that contains less than 200 percent of the applicable Reference Amount shall be considered to be a single-serving container, and the entire content of the product shall be labeled as one serving, except for products that have Reference Amounts of 100 g (or mL) or larger, manufacturers may decide whether a package that contains more than 150 percent but less than 200 percent of the Reference Amount is 1 or 2 servings. Packages sold individually that contain 200 percent or more of the applicable Reference Amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.

(9) A label statement regarding a serving shall be the serving size expressed in common household measures as set forth in paragraphs (b)(2) through (b)(8) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in milliliters and all other foods in grams), except for single-serving containers.

(i) For a single-serving container, the parenthetical metric quantity, which will be presented as part of the net weight statement on the principal display panel, is not required except where nutrition information is required on a drained weight basis according to paragraph (b)(11) of this section. However, if a manufacturer voluntarily provides the metric quantity on products that can be sold as single-servings, then the numerical value provided as part of the serving size declaration must be identical to the metric quantity declaration provided as part of the net quantity of contents statement.

(ii) The gram or milliliter quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g (mL). The gram (mL) quantity between 2 and 5 g (mL) should be rounded to the nearest 0.5 g (mL) and the g (mL) quantity less than 2 g (mL) should be expressed in 0.1-g (mL) increments.

(iii) In addition, serving size may be declared in ounce, in parenthesis, following the metric measure separated by a slash where other common household measures are used as the primary unit for serving size, e.g., 1 slice (28 g/1 oz) for sliced bologna. The ounce quantity equivalent to the metric quantity should be expressed in 0.1-oz increments.

(iv) If a manufacturer elects to use abbreviations for units, the following abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, and oz for ounce.

(10) Determination of the number of servings per container shall be based on the serving size of the product determined by following the procedures described in this section.

(i) The number of servings shall be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings shall be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term "about" (e.g., about 2 servings; about 3.5 servings).

(ii) When the serving size is required to be expressed on a drained solids basis and the number of servings varies because of a natural variation in unit size (e.g., pickled pigs feet), the manufacturer may state the typical number of servings per container (e.g., usually 5 servings).

(iii) For random weight products, a manufacturer may declare "varied" for the number of servings per container provided the nutrition information is based on the Reference Amount expressed in ounces. The manufacturer may provide the typical number of servings in parenthesis following the "varied" statement (e.g., varied (approximately 8 servings per pound)).

(iv) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the number of servings shall be the number of individual packages within the total package.

(v) For packages containing several individually packaged multi-serving units, the number of servings shall be determined by multiplying the number of individual multi-serving units in the total package by the number of servings in each individual unit.

(11) The declaration of nutrient and food component content shall be on the basis of product as packaged or purchased with the exception of

products that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed. Declaration of the nutrient and food component content of products that are packed in liquid which is not customarily consumed shall be based on the drained solids.

(12) Serving size for meal-type products as defined in § 317.313(l) shall be the entire content (edible portion only) of the package.

(13) Another column of figures may be used to declare the nutrient and food component information in the same format as required by § 317.309(e).

(i) Per 100 grams, 100 milliliters, or 1 ounce of the product as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit.

(14) If a product consists of assortments of meat or meat food products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(15) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided*, That the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(c) The declaration of nutrition information on the label or in labeling of a meat or meat food product shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraph (f) or (g) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraph (d) or (e) of this section.

(1) "Calories, total," "Total calories," or "Calories": A statement of the caloric

content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parenthesis immediately following the statement of the caloric content.

(i) Caloric content may be calculated by the following methods. Where either specific or general food factors are used, the factors shall be applied to the actual amount (i.e., before rounding) of food components (e.g., fat, carbohydrate, protein, or ingredients with specific food factors) present per serving.

(A) Using specific Atwater factors (i.e., the Atwater method) given in Table 13, page 25, "Energy Value of Foods—Basis and Derivation," by A. L. Merrill and B. K. Watt, United States Department of Agriculture (USDA), Agriculture Handbook No. 74 (Slightly revised February 1973), which is incorporated by reference. Table 13 of the "Energy Value of Foods—Basis and Derivation," Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the Office of the Federal Register, suite 700, 800 North Capitol Street, NW., Washington, DC, or at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC. Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250-3700;

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9-11, which is incorporated by reference. Pages 9-11, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.);

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly

revised February 1973), pages 9-11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.); or

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of 21 CFR, or by other means, as appropriate.

(ii) "Calories from fat": A statement of the caloric content derived from total fat as defined in paragraph (c)(2) of this section per serving, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that label declaration of "calories from fat" is not required on products that contain less than 0.5 gram of fat per serving and amounts less than 5 calories may be expressed as zero. This statement shall be declared as provided in paragraph (d)(5) of this section.

(iii) "Calories from saturated fat" or "Calories from saturated" (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section per serving may be declared voluntarily, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories from fat as provided in paragraph (d)(5) of this section.

(2) "Fat, total" or "Total fat": A statement of the number of grams of total fat per serving defined as total lipid fatty acids and expressed as triglycerides. Amounts shall be expressed to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(i) "Saturated fat" or "Saturated": A statement of the number of grams of saturated fat per serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat per serving if no claims are made about fat or cholesterol content, and if "calories from saturated fat" is not declared. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5

gram, the content shall be expressed as zero.

(A) "Stearic Acid" (VOLUNTARY): A statement of the number of grams of stearic acid per serving may be declared voluntarily, except that when a claim is made about stearic acid, label declaration shall be required. Stearic acid content shall be indented under saturated fat and expressed to the nearest 0.5 (1/2)-gram increment below 5 grams and the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(B) [Reserved]

(ii) "Polyunsaturated fat" or "Polyunsaturated" (VOLUNTARY): A statement of the number of grams of polyunsaturated fat per serving defined as *cis, cis*-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 317.362(b)(1) for a claim for "fat free," label declaration of polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iii) "Monounsaturated fat" or "Monounsaturated" (VOLUNTARY): A statement of the number of grams of monounsaturated fat per serving defined as *cis*-monounsaturated fatty acids may be declared voluntarily, except that when polyunsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 317.362(b)(1) for a claim for "fat free," label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(3) "Cholesterol": A statement of the cholesterol content per serving expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams of cholesterol per serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol

content as zero. If the product contains 2 to 5 milligrams of cholesterol per serving, the content may be stated as "less than 5 milligrams."

(4) "Sodium": A statement of the number of milligrams of sodium per serving expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(5) "Potassium" (VOLUNTARY): A statement of the number of milligrams of potassium per serving may be declared voluntarily, except that when a claim is made about potassium content, label declaration shall be required. Potassium content shall be expressed as zero when the serving contains less than 5 milligrams of potassium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of potassium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(6) "Carbohydrate, total" or "Total carbohydrate": A statement of the number of grams of total carbohydrate per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, or, if the serving contains less than 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the product. This calculation method is described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 2 and 3, which is incorporated by reference. Pages 2 and 3, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.)

(i) "Dietary fiber": A statement of the number of grams of total dietary fiber per serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required, or, alternatively, the statement "Contains less than 1 gram" or "less than 1 gram" may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(A) "Soluble fiber" (VOLUNTARY): A statement of the number of grams of soluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(B) "Insoluble fiber" (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) "Sugars": A statement of the number of grams of sugars per serving, except that label declaration of sugars content is not required for products that contain less than 1 gram of sugars per serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) "Sugar alcohol" (VOLUNTARY): A statement of the number of grams of sugar alcohols per serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the product, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol or xylitol) or is generally recognized as safe (e.g., sorbitol). In lieu of the term "sugar alcohol," the name of the specific sugar alcohol (e.g., "xylitol") present in the product may be used in the nutrition label, provided

that only one sugar alcohol is present in the product. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iv) "Other carbohydrate" (VOLUNTARY): A statement of the number of grams of other carbohydrate per serving may be declared voluntarily. Other carbohydrate shall be defined as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present), it shall be defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. Other carbohydrate content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) "Protein": A statement of the number of grams of protein per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in products represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a product represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement "not a significant source of protein," or a listing aligned under the column headed "Percent Daily Value" of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as percent of Daily Value. When the protein quality in a product as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard

(casein) for a product represented or purported to be for infants, the statement "not a significant source of protein" shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by appropriate methods of analysis in accordance with § 317.309(h), except when the procedure for a specific food requires another factor.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be for infants or children under 4 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein and aligned under the column headed "Percent Daily Value," and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the product is represented or purported to be for infants and the protein quality value is less than 40 percent of the reference standard.

(ii) The corrected amount of protein (grams) per serving for products represented or purported to be for adults and children 1 or more years of age is equal to the actual amount of protein (grams) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8 in "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990, which is incorporated by reference. Sections 5.4.1, 7.2.1, and 8 of the "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," as published by the Food and Agriculture Organization of the United Nations/World Health Organization, is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the Office of the Federal Register, suite 700, 800 North Capitol Street, NW., Washington, DC, or at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th

and Independence Avenue, SW., Washington, DC. Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250-3700. For products represented or purported to be for infants, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject product's protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, and the RDI for protein for children less than 4 years of age, infants, pregnant women, and lactating women shall be 16 grams, 14 grams, 60 grams, and 65 grams, respectively.

(8) Vitamins and minerals: A statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a percent of the RDI and expressed as percent of Daily Value.

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d) through (g) of this section, products represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women shall use the RDI's that are specified for the intended group. For products represented or purported to be for use by both infants and children under 4 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants from birth to 12 months of age and for children under 4 years of age. Similarly, the percent of Daily Value based on both the RDI values for pregnant women and for lactating women shall be declared separately on products represented or purported to be for use by both pregnant and lactating women. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. All other products shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a percent of the RDI shall include vitamin A, vitamin C, calcium, and iron, in that order, and shall

include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added, or when a claim is made about them. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or in labeling or advertising and the vitamins and minerals are:

(A) Required or permitted in a standardized food (e.g., thiamin, riboflavin, and niacin in enriched flour) and that standardized food is included as an ingredient (i.e., component) in another product; or

(B) Included in a product solely for technological purposes and declared only in the ingredients statement. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(8)(iv) of this section.

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, if vitamin A, vitamin C, calcium, or iron is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement "Not a significant source of \_\_\_\_\_ (listing the vitamins or minerals omitted)" is placed at the bottom of the table of nutrient values.

(iv) The following RDI's and nomenclature are established for the following vitamins and minerals which are essential in human nutrition:

- Vitamin A, 5,000 International Units
- Vitamin C, 60 milligrams
- Calcium, 1.0 gram
- Iron, 18 milligrams
- Vitamin D, 400 International Units
- Vitamin E, 30 International Units
- Thiamin, 1.5 milligrams
- Riboflavin, 1.7 milligrams
- Niacin, 20 milligrams
- Vitamin B<sub>6</sub>, 2.0 milligrams
- Folate, 0.4 milligram
- Vitamin B<sub>12</sub>, 6 micrograms

- Biotin, 0.3 milligram
- Pantothenic acid, 10 milligrams
- Phosphorus, 1.0 gram
- Iodine, 150 micrograms
- Magnesium, 400 milligrams
- Zinc, 15 milligrams
- Copper, 2.0 milligrams

(v) The following synonyms may be added in parenthesis immediately following the name of the nutrient or dietary component:

- Vitamin C—Ascorbic acid
- Thiamin—Vitamin B<sub>1</sub>
- Riboflavin—Vitamin B<sub>2</sub>
- Folate—Folacin
- Calories—Energy

(vi) A statement of the percent of vitamin A that is present as *beta*-carotene may be declared voluntarily. When the vitamins and minerals are listed in a single column, the statement shall be indented under the information on vitamin A. When vitamins and minerals are arrayed horizontally, the statement of percent shall be presented in parenthesis following the declaration of vitamin A and the percent of Daily Value of vitamin A in the product (e.g., "Percent Daily Value: Vitamin A 50 (90 percent as *beta*-carotene)"). When declared, the percentages shall be expressed in the same increments as are provided for vitamins and minerals in paragraph (c)(8)(iii) of this section.

(9) For the purpose of labeling with a percent of the DRV, the following DRV's are established for the following food components based on the reference caloric intake of 2,000 calories:

Food component	Unit of measurement	DRV
Fat .....	grams (g) .....	65
Saturated fatty acids.	do .....	20
Cholesterol .....	milligrams (mg) ..	300
Total carbohydrate.	grams (g) .....	300
Fiber .....	do .....	25
Sodium .....	milligrams (mg) ..	2,400
Potassium .....	do .....	3,500
Protein .....	grams (g) .....	50

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on products in the following format, except on products on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those products on which the simplified format is permitted to be used as provided for in paragraph (f) of this section, on products for infants and children less than 4 years of age as provided for in § 317.400(c), and on products in packages that have a total surface area available to bear labeling of 40 or less square inches as provided for in paragraph (g) of this section.

(i) The nutrition information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the nutrition label shall utilize:

- (A) A single easy-to-read type style,
- (B) Upper and lower case letters,
- (C) At least one point leading (i.e., space between two lines of text) except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section, and

(D) Letters should never touch.

(iii) Information required in paragraphs (d)(3), (d)(5), (d)(7), and (d)(8) of this section shall be in type size no smaller than 8 point. Except for the heading "Nutrition Facts," the information required in paragraphs (d)(4), (d)(6), and (d)(9) of this section and all other information contained within the nutrition label shall be in type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall also be in type no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(4), and (d)(6) of this section (i.e., "Nutrition Facts," "Amount per Serving," and "% Daily Value\*"), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (i.e., Calories, Total fat, Cholesterol, Sodium, Potassium, Total carbohydrate, and Protein), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted by bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate "Amount Per Serving" from the calorie statements required in paragraph (d)(5) of this section and shall separate each nutrient and its corresponding percent of Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent of Daily Value above and below it.

(2) The information shall be presented under the identifying heading of "Nutrition Facts" which shall be set in a type size larger than all other print size in the nutrition label and, except for labels presented according to the format provided for in paragraph (d)(11) of this section, unless impractical, shall be set the full width of the information

provided under paragraph (d)(7) of this section.

(3) Information on serving size shall immediately follow the heading. Such information shall include:

(i) "Serving Size": A statement of the serving size as specified in paragraph (b)(9) of this section.

(ii) "Servings Per Container": The number of servings per container, except that this statement is not required on single-serving containers as defined in paragraph (b)(8) of this section.

(4) A subheading "Amount Per Serving" shall be separated from serving size information by a bar.

(5) Information on calories shall immediately follow the heading "Amount Per Serving" and shall be declared in one line, leaving sufficient space between the declaration of "Calories" and "Calories from fat" to allow clear differentiation, or, if "Calories from saturated fat" is declared, in a column with total "Calories" at the top, followed by "Calories from fat" (indented), and "Calories from saturated fat" (indented).

(6) The column heading "% Daily Value," followed by an asterisk (e.g., "% Daily Value\*"), shall be separated from information on calories by a bar. The position of this column heading shall

allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the left of, and below, this column heading. The column headings "Percent Daily Value," "Percent DV," or "% DV" may be substituted for "% Daily Value."

(7) Except as provided for in paragraph (g) of this section, and except as permitted by § 317.400(d)(2), nutrient information for both mandatory and any voluntary nutrients listed in paragraph (c) of this section that are to be declared in the nutrition label, except vitamins and minerals, shall be declared as follows:

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a "g" for grams or "mg" for milligrams.

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading "% Daily Value" established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been

established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (i.e., %).

(8) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed horizontally (e.g., Vitamin A 4%, Vitamin C 2%, Calcium 15%, Iron 4%) or may be listed in two columns, except that when more than four vitamins and minerals are declared, they may be declared vertically with percentages listed under the column headed "% Daily Value."

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from that list by a hairline.

(i) The footnote shall state: Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total fat .....	Less than .....	65 g .....	80 g
Saturated fat .....	Less than .....	20 g .....	25 g
Cholesterol .....	Less than .....	300 mg .....	300 mg
Sodium .....	Less than .....	2,400 mg .....	2,400 mg
Total carbohydrate .....	.....	300 g .....	375 g
Dietary fiber .....	.....	25 g .....	30 g

(ii) If the percent of Daily Value is given for protein in the Percent of Daily Value column as provided in paragraph (d)(7)(ii) of this section, protein shall be listed under dietary fiber, and a value of 50 g shall be inserted on the same line in the column headed "2,000" and value of 65 g in the column headed "2,500."

(iii) If potassium is declared in the column described in paragraph (d)(7)(i) of this section, potassium shall be listed under sodium and the DRV established in paragraph (c)(9) of this section shall be inserted on the same line in the numeric columns.

(iv) The abbreviations established in paragraph (g)(2) of this section may be used within the footnote.

(10) Caloric conversion information on a per-gram basis for fat, carbohydrate, and protein may be presented beneath the information required in paragraph (d)(9), separated from that information by a hairline. This

information may be presented horizontally (i.e., "Calories per gram: Fat 9, Carbohydrate 4, Protein 4") or vertically in columns.

(11)(i) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in paragraph (d)(9) of this section, the information required in paragraph (d)(9) may be moved to the right of the column required in paragraph (d)(7)(ii) of this section and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(ii) If the space beneath the mandatory declaration of iron is not adequate to accommodate any remaining vitamins and minerals to be declared or the information required in paragraph (d)(9)

of this section, the remaining information may be moved to the right and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information given to the left. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(iii) If there is not sufficient continuous vertical space (i.e., approximately 3 inches) to accommodate the required components of the nutrition label up to and including the mandatory declaration of iron, the nutrition label may be presented in a tabular display in which the footnote required by paragraph (d)(9) of the section is given to the far right of the label, and additional vitamins and minerals beyond the four that are required (i.e., vitamin A, vitamin C, calcium, and iron) are

arrayed horizontally following declarations of the required vitamins and minerals.

(12) The following sample label illustrates the provisions of paragraph (d) of this section:

BILLING CODE 3410-DM-P

<b>Nutrition Facts</b>	
Serving Size 1 cup (228g)	
Servings Per Container 2	
<b>Amount Per Serving</b>	
<b>Calories 260</b> <b>Calories from Fat 120</b>	
<b>% Daily Value*</b>	
<b>Total Fat</b> 13g	<b>20%</b>
Saturated Fat 5g	<b>25%</b>
<b>Cholesterol</b> 30mg	<b>10%</b>
<b>Sodium</b> 660mg	<b>28%</b>
<b>Total Carbohydrate</b> 31g	<b>10%</b>
Dietary Fiber 0g	<b>0%</b>
Sugars 5g	
<b>Protein</b> 5g	
Vitamin A 4%	• Vitamin C 2%
Calcium 15%	• Iron 4%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:	
	Calories: 2,000    2,500
Total Fat	Less than 65g    80g
Sat Fat	Less than 20g    25g
Cholesterol	Less than 300mg    300mg
Sodium	Less than 2,400mg    2,400mg
Total Carbohydrate	300g    375g
Dietary Fiber	25g    30g
Calories per gram:	
Fat 9 • Carbohydrate 4 • Protein 4	

BILLING CODE 3410-DM-C

(13)(i) Nutrition labeling on the outer label of packages of meat or meat food products that contain two or more

products in the same packages (e.g., variety packs) or of packages that are used interchangeably for the same type

of food (e.g., meat salad containers) may use an aggregate display.

(ii) Aggregate displays shall comply with format requirements of paragraph

(d) of this section to the maximum extent possible, except that the identity of each food shall be specified to the right of the "Nutrition Facts" title, and both the quantitative amount by weight (i.e., g/mg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food.

(14) When nutrition labeling appears in a second language, the nutrition information may be presented in a separate nutrition label for each language or in one nutrition label with the information in the second language following that in English. Numeric characters that are identical in both languages need not be repeated (e.g., "Protein/Proteínas 2 g"). All required information must be included in both languages.

(e) Nutrition information may be presented for two or more forms of the same product (e.g., both "raw" and "cooked") or for common combinations of foods as provided for in paragraph (b) of this section, or for different units (e.g., per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDI's are established (e.g., both infants and children less than 4 years of age) as provided for in paragraph (c)(8)(i) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the subheading of "Amount Per Serving," there shall be two or more column headings accurately describing the forms of the

same product (e.g., "raw" and "roasted"), the combinations of foods, the units, or the RDI groups that are being declared. The column representing the product as packaged and according to the label serving size based on the Reference Amount in § 317.312(b) shall be to the left of the numeric columns.

(2) When the dual labeling is presented for two or more forms of the same product, for combinations of foods, or for different units, total calories and calories from fat (and calories from saturated fat, when declared) shall be listed in a column and indented as specified in paragraph (d)(5) of this section with quantitative amounts declared in columns aligned under the column headings set forth in paragraph (e)(1) of this section.

(3) Quantitative information by weight required in paragraph (d)(7)(i) of this section shall be specified for the form of the product as packaged and according to the label serving size based on the Reference Amount in § 317.312(b).

(i) Quantitative information by weight may be included for other forms of the product represented by the additional column(s) either immediately adjacent to the required quantitative information by weight for the product as packaged and according to the label serving size based on the Reference Amount in § 317.312(b) or as a footnote.

(A) If such additional quantitative information is given immediately adjacent to the required quantitative information, it shall be declared for all nutrients listed and placed immediately following and differentiated from the

required quantitative information (e.g., separated by a comma). Such information shall not be put in a separate column.

(B) If such additional quantitative information is given in a footnote, it shall be declared in the same order as the nutrients are listed in the nutrition label. The additional quantitative information may state the total nutrient content of the product identified in the second column or the nutrient amounts added to the product as packaged for only those nutrients that are present in different amounts than the amounts declared in the required quantitative information. The footnote shall clearly identify which amounts are declared. Any subcomponents declared shall be listed parenthetically after principal components (e.g., 1/2 cup skim milk contributes an additional 40 calories, 65 mg sodium, 6 g total carbohydrate (6 g sugars), and 4 g protein).

(ii) Total fat and its quantitative amount by weight shall be followed by an asterisk (or other symbol) (e.g., "Total fat (2 g)\*") referring to another asterisk (or symbol) at the bottom of the nutrition label identifying the form(s) of the product for which quantitative information is presented.

(4) Information required in paragraphs (d)(7)(ii) and (d)(8) of this section shall be presented under the subheading "% DAILY VALUE" and in columns directly under the column headings set forth in paragraph (e)(1) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

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<b>Nutrition Facts</b>		
Serving Size 1/12 package (44g, about 1/4 cup dry mix)		
Servings Per Container 12		
Amount Per Serving	Mix	Baked
<b>Calories</b>	190	280
Calories from Fat	45	140
% Daily Value**		
<b>Total Fat 5g*</b>	<b>8%</b>	<b>24%</b>
Saturated Fat 2g	10%	13%
<b>Cholesterol 0mg</b>	<b>0%</b>	<b>23%</b>
<b>Sodium 300mg</b>	<b>13%</b>	<b>13%</b>
<b>Total Carbohydrate 34g</b>	<b>11%</b>	<b>11%</b>
Dietary Fiber 0g	0%	0%
Sugars 18g		
<b>Protein 2g</b>		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%
* Amount in Mix		
** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:		
	Calories:	2,000    2,500
Total Fat	Less than	65g    80g
Sat Fat	Less than	20g    25g
Cholesterol	Less than	300mg    300mg
Sodium	Less than	2,400mg    2,400mg
Total Carbohydrate		300g    375g
Dietary Fiber		25g    30g
Calories per gram:		
Fat 9 • Carbohydrate 4 • Protein 4		

## BILLING CODE 3410-DM-C

(f)(1) Nutrition information may be presented in a simplified format as set forth herein when any required nutrients, other than the core nutrients (i.e., calories, total fat, sodium, total carbohydrate, and protein), are present in insignificant amounts. An insignificant amount shall be defined as that amount that may be rounded to zero in nutrition labeling, except that for

total carbohydrate, dietary fiber, sugars and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include information on the following nutrients:

- (i) Total calories, total fat, total carbohydrate, sodium, and protein;
- (ii) Any of the following that are present in more than insignificant amounts: Calories from fat, saturated fat,

cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron; and

(iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added in fortified or fabricated foods.

(3) Other nutrients that are naturally present in the product in more than insignificant amounts may be

voluntarily declared as part of the simplified format.

(4) Any required nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the tabular listing, provided that the following statement is included at the bottom of the nutrition label, "Not a significant source of \_\_\_\_\_." The blank shall be filled in with the appropriate nutrient or food component. Alternatively, amounts of vitamins and minerals present in insignificant amounts may be declared by the use of an asterisk (or symbol) that is placed at the bottom of the table of nutrient values and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)."

(5) Except as provided for in paragraph (g) of this section and in § 317.400(c) and (d), nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote required in paragraph (d)(9) of this section is not required. When the footnote is omitted, an asterisk shall be placed at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value."

(g) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (c) through (f) of this section and § 317.302(a) by one or more of the following means:

(1)(i) Presenting the required nutrition information in a tabular or linear (i.e., string) fashion, rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches, or if the product has a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Nutrition information may be given in a linear fashion only if the package shape or size will not accommodate a tabular display.

(ii) When nutrition information is given in a linear display, the nutrition information shall be set off in a box by the use of a hairline. The percent Daily Value is separated from the quantitative amount declaration by the use of parenthesis, and all nutrients, both principal components and subcomponents, are treated similarly. Bolding is required only on the title "Nutrition Facts" and is allowed for

nutrient names for "Calories," "Total fat," "Cholesterol," "Sodium," "Total carbohydrate," and "Protein."

(2) Using any of the following abbreviations:

Serving size—Serv size  
 Servings per container—Servings  
 Calories from fat—Fat cal  
 Calories from saturated fat—Sat fat cal  
 Saturated fat—Sat fat  
 Monounsaturated fat—Monounsat fat  
 Polyunsaturated fat—Polyunsat fat  
 Cholesterol—Cholest  
 Total carbohydrate—Total carb  
 Dietary fiber—Fiber  
 Soluble fiber—Sol fiber  
 Insoluble fiber—Insol fiber  
 Sugar alcohol—Sugar alc  
 Other carbohydrate—Other carb

(3) Omitting the footnote required in paragraph (d)(9) of this section and placing another asterisk at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value."

(4) Presenting the required nutrition information on any other label panel.

\* \* \* \* \*

6. Section 317.312 is amended by redesignating paragraph (d) as (g), correcting the spelling of the word "Nationwide" in footnote 1 of Table 2 in paragraph (b), revising paragraph (a), and adding new paragraphs (d), (e), and (f) to read as follows:

*§ 317.312 Reference amounts customarily consumed per eating occasion.*

(a) The general principles followed in arriving at the reference amounts customarily consumed per eating occasion (Reference Amount(s)), as set forth in paragraph (b) of this section, are:

(1) The Reference Amounts are calculated for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These Reference Amounts are based on data set forth in appropriate national food consumption surveys.

(2) The Reference Amounts are calculated for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These Reference Amounts are based on data set forth in appropriate national food consumption surveys. Such Reference Amounts are to be used only when the product is specially formulated or processed for

use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, the mean, median, and mode of the consumed amount per eating occasion were considered.

(5) When survey data were insufficient, FSIS took various other sources of information on serving sizes of food into consideration. These other sources of information included:

- (i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;
- (ii) Serving sizes recommended in comments;
- (iii) Serving sizes used by manufacturers and grocers; and
- (iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the Reference Amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The Reference Amount is based on the major intended use of the product (e.g., a mixed dish measurable with a cup as a main dish and not as a side dish).

(8) The Reference Amounts for products that are consumed as an ingredient of other products, but that may also be consumed in the form in which they are purchased (e.g., ground beef), are based on use in the form purchased.

(9) FSIS sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform Reference Amount.

\* \* \* \* \*

(d) If a product requires further preparation, e.g., cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a Reference Amount for the product in the prepared form, then the Reference Amount for the unprepared product shall be determined using the following rules:

(1) Except as provided for in paragraph (d)(2) of this section, the Reference Amount for the unprepared product shall be the amount of the

unprepared product required to make the Reference Amount for the prepared product as established in paragraph (b) of this section.

(2) For products where the entire contents of the package is used to prepare one large discrete unit usually divided for consumption, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the fraction of the large discrete unit closest to the Reference Amount for the prepared product as established in paragraph (b) of this section.

(e) The Reference Amount for an imitation or substitute product or altered product as defined in § 317.313(d), such as a "low calorie" version, shall be the same as for the product for which it is offered as a substitute.

(f) The Reference Amounts set forth in paragraphs (b) through (e) of this section shall be used in determining whether a product meets the criteria for nutritional claims. If the serving size declared on the product label differs from the Reference Amount, and the product meets the criteria for the claim only on the basis of the Reference Amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the Reference Amount as it appears in paragraph (b) of this section followed, in parentheses, by the amount in common household measure if the Reference Amount is expressed in measures other than common household measures.

\* \* \* \* \*

7. Section 317.313 is amended by revising paragraphs (a), (b), (g), (i), (j), (k), (p), and (q)(4) and adding new paragraphs (c), (d), (e), and (f) to read as follows:

**§ 317.313 Nutrient content claims; general principles.**

(a) This section applies to meat or meat food products that are intended for human consumption and that are offered for sale.

(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 317.309, may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this subpart.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the product, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the product or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the product, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on products intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in subpart B of this part.

(4) Reasonable variations in the spelling of the terms defined in applicable provisions in this subpart and their synonyms are permitted provided these variations are not misleading (e.g., "hi" or "lo").

(c) Information that is required or permitted by § 317.309 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A "substitute" product is one that may be used interchangeably with another product that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an "imitation."

(1) If there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., "not recommended for frying").

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 317.2(h) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch

minimum height, except as permitted by § 317.400(d)(2).

(e)(1) Because the use of a "free" or "low" claim before the name of a product implies that the product differs from other products of the same type by virtue of its having a lower amount of the nutrient, only products that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the product, remove the nutrient from the product, or not include the nutrient in the product, may bear such a claim (e.g., "low sodium beef noodle soup").

(2) Any claim for the absence of a nutrient in a product, or that a product is low in a nutrient when the product has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the product inherently meets the criteria and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches (e.g., "lard, a sodium free food").

(f) A nutrient content claim shall be in type size and style no larger than two times that of the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) Labeling information required in §§ 317.313, 317.354, 317.356, 317.360, 317.361, 317.362, and 317.380, whose type size is not otherwise specified, is required to be in letters and/or numbers no less than 1/16 inch in height, except as permitted by § 317.400(d)(2).

(h) [Reserved]

(i) Except as provided in § 317.309 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is consistent with a definition for a claim, as provided in subpart B of this part, for the nutrient that the label addresses. Such a claim might be, "less than 10 g of fat per serving;"

(2) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the product is not "low" in or a "good source" of the nutrient, such as "only 200 milligrams (mg) sodium per serving, not a low sodium product." The disclaimer must be in easily legible print or type and in a size no less than required by § 317.2(h) for the net quantity of contents, except where the size of the claim is less than two times

the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2);

(3) The statement does not in any way implicitly characterize the level of the nutrient in the product and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

(4) "Percent fat free" claims are not authorized by this paragraph. Such claims shall comply with § 317.362(b)(6).

(j) A product may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference product. These statements shall be known as "relative claims" and include "light," "reduced," "less" (or "fewer"), and "more" claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the product must be compared to an amount of nutrient in an appropriate reference product as specified in this paragraph (j).

(i)(A) For "less" (or "fewer") and "more" claims, the reference product may be a dissimilar product within a product category that can generally be substituted for one another in the diet or a similar product.

(B) For "light," "reduced," and "added" claims, the reference product shall be a similar product, and

(ii)(A) For "light" claims, the reference product shall be representative of the type of product that includes the product that bears the claim. The nutrient value for the reference product shall be representative of a broad base of products of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the product type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than "light," including "less" and "more" claims, the reference product may be the same as that provided for "light" in paragraph (j)(1)(ii)(A) of this section or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same

geographic area by the same business entity or by one entitled to use its trade name, provided the name of the competitor is not used on the labeling of the product. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either the values declared in nutrition labeling or the actual nutrient values, provided that the resulting labeling is internally consistent (i.e., that the values stated in the nutrition information, the nutrient values in the accompanying information, and the declaration of the percentage of nutrient by which the product has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

(2) For products bearing relative claims:

(i) The label or labeling must state the identity of the reference product and the percent (or fraction) of the amount of the nutrient in the reference product by which the nutrient has been modified, (e.g., "50 percent less fat than 'reference product'" or "1/3 fewer calories than 'reference product'"); and

(ii) This information shall be immediately adjacent to the most prominent claim in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 317.2(h) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim, but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2).

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving size with that in the reference product; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition information.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the requirement for a "low" claim for that nutrient.

(k) The term "modified" may be used in the statement of identity of a product that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., "modified fat 'product'"). This statement of identity must be immediately followed by the comparative statement such as "contains 35 percent less fat than 'reference product.'" The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

\* \* \* \* \*

(p)(1) Unless otherwise specified, the reference amount customarily consumed set forth in § 317.312(b) through (e) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 317.312(f) (e.g., "very low sodium, 35 mg or less per 55 grams").

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size that is no less than that required by § 317.2(h) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the criteria statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2).

(q) \* \* \*

(4) The requirements of this section do not apply to infant formulas and medical foods, as described in 21 CFR 101.13(q)(4).

\* \* \* \* \*

8. Section 317.345 is amended by revising the section reference in paragraph (c) from "§ 317.309(g)" to "§ 317.309(f)" and revising paragraphs (a)(2) introductory text, (a)(2)(ii) and (a)(2)(iii) to read as follows:

**§ 317.345 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.**

(a) \* \* \*

(2) A retailer may choose to provide nutrition information at the point-of-purchase, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials all of the requirements of the mandatory nutrition labeling program apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials:

(i) \* \* \*

(ii) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in § 317.309(c)(8)) and footnote required by § 317.309(d)(9) may be omitted; and

(iii) The point-of-purchase materials are not subject to any of the format requirements.

\* \* \* \* \*

9. Section 317.354 is revised to read as follows:

**§ 317.354 Nutrient content claims for “good source,” “high,” and “more.”**

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a product in relation to the Reference Daily Intake (RDI) or Daily Reference Value (DRV) established for that nutrient (excluding total carbohydrate) in § 317.309(c), may only be made on the label or in labeling of the product 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 § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *“High” claims.* (1) The terms “high,” “rich in,” or “excellent source of” may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), provided that the product 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 or in labeling of a meal-type product as defined in § 317.313(l), 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 meal is high in vitamin C”).

(c) *“Good Source” claims.* (1) The terms “good source,” “contains,” or “provides” may be used on the label or in labeling of products, except meal-type products as described in § 317.313(l), provided that the product 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 or in labeling of a meal-type product as defined in § 317.313(l), 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 meal 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, i.e., that the product is high in fiber, a good source of fiber, or that the product contains “more” fiber, and the product is not “low” in total fat as defined in § 317.362(b)(2) or, in the case of a meal-type product, is not “low” in total fat as defined in § 317.362(b)(3), then the labeling shall disclose the level of total fat per labeled serving size (e.g., “contains 12 grams (g) of fat per serving”); and

(2) The disclosure shall appear in immediate proximity to such claim and be in a type size no less than one-half the size of the claim.

(e) *“More” claims.* (1) A relative claim using the terms “more” and “added” may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a product, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (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 ‘reference product’”); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “fiber content of ‘reference product’ is 1 g per serving; ‘this product’ contains 4 g per serving”).

(2) A relative claim using the terms “more” and “added” may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (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 per 3 ounces (oz) than does ‘reference product’”), and

(B) Quantitative information comparing the level of the nutrient in the meal-type product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “fiber content of ‘reference product’ is 2 g per 3 oz; ‘this product’ contains 5 g per 3 oz”).

10. Section 317.356 is revised to read as follows:

**§ 317.356 Nutrient content claims for “light” or “lite.”**

(a) *General requirements.* A claim using the terms “light” or “lite” to describe a product may only be made on the label or in labeling of the product 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 § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *“Light” claims.* The terms “light” or “lite” may be used on the label or in

labeling of products, except meal-type products as defined in § 317.313(l), without further qualification, provided that:

(1) If the product 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 product as described in § 317.313(j)(1); or

(2) If the product derives less than 50 percent of its calories from fat:

(i) The number of calories is reduced by at least one-third (33 $\frac{1}{3}$  percent) per reference amount customarily consumed compared to an appropriate reference product as described in § 317.313(j)(1); or

(ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the appropriate reference product as described in § 317.313(j)(1); and

(3) As required in § 317.313(j)(2) for relative claims:

(i) The identity of the reference product 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., “ $\frac{1}{3}$  fewer calories and 50 percent less fat than the market leader”); and

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “lite ‘this product’—200 calories, 4 grams (g) fat; regular ‘reference product’—300 calories, 8 g fat per serving”); and

(iii) If the labeled product 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 product for which the reference product meets the definition of “low fat” and “low calorie.”

(c)(1)(i) A product for which the reference product contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the terms “light” or “lite” without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference product; and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., “50

percent less sodium than the market leader”); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “lite ‘this product’—500 milligrams (mg) sodium per serving; regular ‘reference product’—1,000 mg sodium per serving”).

(2)(i) A product for which the reference product contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the terms “light in sodium” or “lite in sodium” if it is reduced by 50 percent or more in sodium content compared to the reference product, 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 § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., “50 percent less sodium than the market leader”); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., or “lite ‘this product’—170 mg sodium per serving; regular ‘reference product’—350 mg per serving”).

(3) Except for meal-type products as defined in § 317.313(l), a “light in sodium” claim may not be made on a product for which the reference product meets the definition of “low in sodium.”

(d)(1) The terms “light” or “lite” may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product meets the definition of:

(A) “Low in calories” as defined in § 317.360(b)(3); or

(B) “Low in fat” as defined in § 317.362(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 terms “light in sodium” or “lite in sodium” may be used on the

label or in labeling of a meal-type product as defined in § 317.313(l), provided that the product meets the definition of “low in sodium” as defined in § 317.361(b)(5)(i); and

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

(3) The term “light” or “lite” may be used in the brand name of a product to describe the sodium content, provided that:

(i) The product is reduced by 50 percent or more in sodium content compared to the reference product;

(ii) A statement specifically stating that the product is “light in sodium” or “lite in sodium” appears:

(A) Contiguous to the brand name; and

(B) In uniform type size, style, color, and prominence as the product name; and

(iii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim; and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information.

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

(1) It describes some physical or organoleptic attribute of the product 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 product to reflect a physical or organoleptic attribute 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 product

as described in § 317.313(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not "low in sodium" as defined in § 317.361(b)(4), the statement "not a low sodium food," shall appear adjacent to the nutrition information and the information required to accompany a relative claim shall appear on the label or labeling as specified in § 317.313(j)(2).

11. Section 317.360 is revised to read as follows:

**§ 317.360 Nutrient content claims for calorie content.**

(a) *General requirements.* A claim about the calorie or sugar content of a product may only be made on the label or in labeling of the product 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 § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *Calorie content claims.* (1) The terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietarily insignificant source of calories" may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 calories per reference amount customarily consumed and per labeled serving size; and

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

(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 products, except meal-type products as defined in § 317.313(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and does not provide more than 40 calories per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and does not provide more than 40 calories per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted

before typical consumption with water or a diluent containing an insignificant amount, as defined in § 317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the "as prepared" form).

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

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains 120 calories or less 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 caloric content, it is labeled to clearly refer to all products 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 labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., lower calorie 'product'— "33 $\frac{1}{3}$  percent fewer calories than our regular 'product'"); and

(B) Quantitative information comparing the level of calories in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "calorie content has been reduced from 150 to 100 calories per serving").

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of products if the reference product 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 labeling of a meal-type

product as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent fewer calories per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., "calorie reduced 'product', 25% less calories per ounce (oz) (or 3 oz) than our regular 'product'"); and

(B) Quantitative information comparing the level of calories in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "calorie content has been reduced from 110 calories per 3 oz to 80 calories per 3 oz").

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of products if the reference product meets the definition for "low calorie."

(c) *Sugar content claims.* (1) 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" may reasonably be expected to be regarded by consumers as terms that represent that the product 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 product may not be labeled with such terms unless:

(i) The product contains less than 0.5 g of sugars, as defined in § 317.309(c)(6)(ii), per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 0.5 g of sugars per labeled serving size;

(ii) The product 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 ingredients 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

(B) Such term is immediately accompanied, each time it is used, by either the statement "not a reduced calorie product," "not a low calorie product," 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 § 317.309(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging;

(ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice;

(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 product, and a functionally insignificant increase in sugars results;

(iv) The product that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement that the product is not "low calorie" or "calorie reduced" (unless the product meets the requirements for a "low" or "reduced calorie" product) 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 product, including products intended specifically for infants and children less than 2 years of age, is unsweetened or contains no added sweeteners in the case of a product that contains apparent substantial inherent sugar content, e.g., juices.

(4) 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 products, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less sugars per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., "this product contains 25

percent less sugar than our regular product"); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "sugar content has been lowered from 8 g to 6 g per serving").

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less sugars per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced sugar 'product'—25% less sugar than our regular 'product'"); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz").

12. Section 317.361 is revised to read as follows:

**§ 317.361 Nutrient content claims for the sodium content.**

(a) *General requirements.* A claim about the level of sodium in a product may only be made on the label or in labeling of the product 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 § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(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 "dietarily insignificant source of sodium" may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per

labeled serving size or, in the case of a meal-type product, less than 5 mg of sodium per labeled serving size;

(ii) The product contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium unless the listing of the ingredient in the ingredients 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) 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 products of its type and not merely to the particular brand to which the label attaches.

(2) The terms "very low sodium" or "very low in sodium" may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and contains 35 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 35 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 317.309(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 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 products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), 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 products of its type and not merely

to the particular brand to which the label attaches.

(4) The terms "low sodium," "low in sodium," "little sodium," "contains a small amount of sodium," or "low source of sodium" may be used on the label and in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

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

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 140 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 317.309(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 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 products of its type and not merely to the particular brand to which the label attaches.

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains 140 mg or less sodium per 100 g of product; 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 products 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 products, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two

products are declared in immediate proximity to the most prominent such claim (e.g., "reduced sodium 'product', 50 percent less sodium than regular 'product'"); and

(B) Quantitative information comparing the level of sodium in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "sodium content has been lowered from 300 to 150 mg per serving").

(iii) Claims described in paragraph (b)(6) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product 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 labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less sodium per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced sodium 'product'—30% less sodium per 3 oz than our 'regular product'"); and

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "sodium content has been reduced from 220 mg per 3 oz to 150 mg per 3 oz").

(iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in labeling of products if the nutrient content of the reference product 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 products only if the product 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 products only if:

(i) No salt is added during processing;

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

(iii) If the product is not sodium free, the statement, "not a sodium free product" or "not for control of sodium in the diet" appears adjacent to the nutrition information of the product bearing the claim.

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

13. Section 317.362 is revised to read as follows:

**§ 317.362 Nutrient content claims for fat, fatty acids, and cholesterol content.**

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a product may only be made on the label or in labeling of products 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 § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *Fat content claims.* (1) The terms "fat free," "free of fat," "no fat," "zero fat," "without fat," "nonfat," "trivial source of fat," "negligible source of fat," or "dietarily insignificant source of fat" may be used on the label or in labeling of products, provided that:

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

(ii) The product 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 ingredients 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) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the

particular brand to which the label attaches.

(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 and in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

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

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the "as prepared" form).

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

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains 3 g or less of total fat per 100 g of product 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 the fat content, it is labeled to clearly refer to all products 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 labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two

products are declared in immediate proximity to the most prominent such claim (e.g., "reduced fat—50 percent less fat than our regular 'product'"); and

(B) Quantitative information comparing the level of fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "fat content has been reduced from 8 g to 4 g per serving").

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product 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 labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less fat per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

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

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent such claim or to the nutrition information (e.g., "fat content has been reduced from 8 g per 3 oz to 5 g per 3 oz").

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

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

(i) The product 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 products 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.

(iv) A synonym for "\_\_\_\_\_ percent fat free" is "\_\_\_\_\_ percent lean."

(c) *Fatty acid content claims.* (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 labeling of products, provided that:

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

(ii) The product contains no ingredient that is generally understood by consumers to contain saturated fat unless the listing of the ingredient in the ingredients 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) 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 products of its type and not merely to the particular brand to which the label attaches.

(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 labeling of products, except meal-type products as defined in § 317.313(l), provided that:

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

(ii) If the product 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 products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (c)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains 1 g or less of saturated fat 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 products 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 labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less saturated fat per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced saturated fat 'product', contains 50 percent less saturated fat than the national average for 'product'"); and

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "saturated fat reduced from 3 g to 1.5 g per serving").

(iii) Claims described in paragraph (c)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product 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 labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less saturated fat per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced saturated fat 'product'," "50 percent less saturated fat than our regular 'product'"); and

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "saturated fat content

has been reduced from 2.5 g per 3 oz to 1.5 g per 3 oz").

(iii) Claims described in paragraph (c)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product 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 labeling of products, provided that:

(i) The product contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product as defined in § 317.313(l), less than 2 mg of cholesterol per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredients 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";

(iii) The product contains 2 g or less of saturated fat per reference amount customarily consumed or, in the case of a meal-type product as defined in § 317.313(l), 2 g or less of saturated fat per labeled serving size; and

(iv) If the product 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 products of its type and not merely to the particular brand to which it attaches; or

(v) If the product meets these conditions only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 317.313(j)(1) and for which it substitutes as described in § 317.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product 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 'product', contains 100

percent less cholesterol than 'reference product'"); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "contains no cholesterol compared with 30 mg in one serving of 'reference product'").

(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 labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i)(A) If the product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp:

(1) The product contains 20 mg or less of cholesterol per reference amount customarily consumed; and

(2) The product contains 2 g or less of saturated fat per reference amount customarily consumed; or

(B) If the product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less:

(1) The product contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the "as prepared" form); and

(2) The product contains 2 g or less of saturated fat per reference amount customarily consumed.

(ii) If the product 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 products of its type and not merely to the particular brand to which the label attaches; or

(iii) If the product contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 317.313(j)(1) and for which it substitutes as described in § 317.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product 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 'product', contains 85 percent less cholesterol than our regular 'product'"); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "cholesterol lowered from 30 mg to 5 mg per serving").

(3) The terms defined in paragraph (d)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains 20 mg or less of cholesterol per 100 g of product;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) If the product 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 products of its type and not merely to the particular brand to which the label attaches.

(4) The terms "reduced cholesterol," "reduced in cholesterol," "cholesterol reduced," "less cholesterol," "lower cholesterol," or "lower in cholesterol" may be used on the label or in labeling of products or products that substitute for those products as specified in § 317.313(d), excluding meal-type products as defined in § 317.313(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 317.313(j)(1) and for which it substitutes as described in § 317.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per reference amount customarily consumed; and

(iii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product 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 'reference product'"); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "cholesterol lowered from 55 mg to 30 mg per serving").

(iv) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product 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 labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 317.313(j)(1) and for which it substitutes as described in § 317.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product 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 than 'reference product'"); and

(B) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz).

(iv) Claims described in paragraph (d)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product 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 a product, provided that the product contains less than 10 g of fat, 4.5 g or less of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 317.313(l).

(2) The term "extra lean" may be used on the label or in labeling of a product, provided that the product contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 317.313(l).

#### § 317.363 [Amended]

14. Section 317.363 is amended by revising the section reference in paragraphs (b)(2) introductory text and (b)(3) introductory text from "§ 317.309(g)(1)" to "§ 317.309(f)(1)."

#### § 317.369 [Amended]

15. Section 317.369 is amended by adding the word "meat" before the words "food products" in the last sentence of paragraph (k)(5) introductory text; by replacing the word "preceding" in paragraph (k)(5)(i)(A) with the word "proceeding"; and by replacing the word "application" in the second sentence of paragraph (k)(5)(i)(B) with the word "applicant".

16. Section 317.380 is amended by revising paragraphs (e) and (f) to read as follows:

#### § 317.380 Label statements relating to usefulness in reducing or maintaining body weight.

\* \* \* \* \*

(e) "*Label terms suggesting usefulness as low calorie or reduced calorie foods*".

(1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, a product may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false or misleading, and the product is labeled "low calorie" or "reduced calorie" or bears another comparative calorie claim in compliance with the applicable provisions in this subpart.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term "diet" that clearly shows that the product is offered solely for a dietary use other than regulating body weight, e.g., "for low sodium diets."

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other product that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) "*Sugar free*" and "*no added sugar*". Criteria for the use of the terms "sugar free" and "no added sugar" are provided for in § 317.360(c).

#### § 317.400 [Amended]

17. Section 317.400 is amended by adding the words "meat or" before the words "meat food products" in paragraph (a) introductory text; by revising the section reference in

paragraph (c)(2)(iii) from “§ 317.309(e)” to “§ 317.309(d)(6)”; and by revising the words “at 21 CFR 101.9(d)(9)” in paragraph (c)(2)(v) to the words “in § 317.309(d)(9).”

### PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

18. The authority citation for part 381 continues to read as follows:

**Authority:** 7 U.S.C. 138F; 7 U.S.C. 450; 21 U.S.C. 451–470; 7 CFR 2.17, 2.55.

#### § 381.400 [Amended]

19. Section 381.400 is amended by adding the words “intended for human consumption and offered for sale” after the words “poultry products” in paragraph (a).

20. Section 381.409 is amended by revising the section reference in the fifth sentence of paragraph (h)(2) from “§ 381.409(b)” to “§ 381.409(c)” and revising paragraphs (a) through (g) to read as follows:

#### § 381.409 Nutrition label content.

(a) All nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(b)(1) The term “serving” or “serving size” means an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the product. When the product is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

(2) Except as provided in paragraphs (b)(8), (b)(12), and (b)(14) of this section and for products that are intended for weight control and are available only through a weight-control or weight-maintenance program, the serving size declared on a product label shall be determined from the “Reference Amounts Customarily Consumed Per Eating Occasion—General Food Supply” (Reference Amount(s)) that appear in § 381.412(b) using the procedures described in this paragraph (b). For products that are both intended for weight control and available only through a weight-control program, a manufacturer may determine the serving size that is consistent with the meal plan of the program. Such products must bear a statement, “for sale only through the \_\_\_\_\_ program” (fill in the blank with the name of the appropriate weight-control program, e.g., Smith’s Weight Control), on the principal

display panel. However, the Reference Amounts in § 381.412(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrition claims.

(3) The declaration of nutrient and food component content shall be on the basis of the product “as packaged” for all products, except that single-ingredient, raw products may be declared on the basis of the product “as consumed” as set forth in § 381.445(a)(1). In addition to the required declaration on the basis of “as packaged” for products other than single ingredient, raw products, the declaration may also be made on the basis of “as consumed,” provided that preparation and cooking instructions are clearly stated.

(4) For products in discrete units (e.g., chicken wings, and individually packaged products within a multi-serving package), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., chicken wings and barbecue sauce), the serving size shall be declared as follows:

(i) If a unit weighs 50 percent or less of the Reference Amount, the serving size shall be the number of whole units that most closely approximates the Reference Amount for the product category.

(ii) If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may declare one unit or two units as the serving size.

(iii) If a unit weighs 67 percent or more but less than 200 percent of the Reference Amount, the serving size shall be one unit.

(iv) If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare one unit as the serving size if the whole unit can reasonably be consumed at a single eating occasion.

(v) For products that have Reference Amounts of 100 grams (or milliliter) or larger and are individual units within a multi-serving package, if a unit contains more than 150 percent but less than 200 percent of the Reference Amount, the manufacturer may decide whether to declare the individual unit as 1 or 2 servings.

(vi) For products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., chicken wings and barbecue sauce), the serving size may be the number of

discrete units represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product as determined in § 381.412(c).

(vii) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the serving size shall be 1 unit.

(5) For products in large discrete units that are usually divided for consumption (e.g., pizza, pan of poultry lasagna), for unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g., pizza kit), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a large discrete unit usually divided for consumption, the serving size shall be the fractional slice of the ready-to-eat product (e.g.,  $\frac{1}{8}$  quiche,  $\frac{1}{4}$  pizza) that most closely approximates the Reference Amount for the product category. The serving size may be the fraction of the package used to make the Reference Amount for the unprepared product determined in § 381.412(d) or the fraction of the large discrete unit represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount of the combined product determined in § 381.412(c). In expressing the fractional slice, manufacturers shall use  $\frac{1}{2}$ ,  $\frac{1}{3}$ ,  $\frac{1}{4}$ ,  $\frac{1}{5}$ ,  $\frac{1}{6}$ , or smaller fractions that can be generated by further division by 2 or 3.

(6) For nondiscrete bulk products (e.g., whole turkey, turkey breast, ground poultry), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a bulk product (e.g., turkey breast and gravy), the serving size shall be the amount in household measure that most closely approximates the Reference Amount for the product category and may be the amount of the bulk product represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product determined in § 381.412(c).

(7) For labeling purposes, the term “common household measure” or “common household unit” means cup, tablespoon, teaspoon, piece, slice, fraction (e.g.,  $\frac{1}{4}$  pizza), ounce (oz), or other common household equipment used to package food products (e.g., jar

or tray). In expressing serving size in household measures, except as specified in paragraphs (b)(7)(iv), (v), and (vi) of this section, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate. Cups shall be expressed in  $\frac{1}{4}$ - or  $\frac{1}{3}$ -cup increments, tablespoons in whole number of tablespoons for quantities less than  $\frac{1}{4}$  cup but greater than or equal to 2 tablespoons (tbsp), 1,  $1\frac{1}{3}$ ,  $1\frac{1}{2}$ , or  $1\frac{2}{3}$  tbsp for quantities less than 2 tbsp but greater than or equal to 1 tbsp, and teaspoons in whole number of teaspoons for quantities less than 1 tbsp but greater than or equal to 1 teaspoon (tsp), and in  $\frac{1}{4}$ -tsp increments for quantities less than 1 tsp.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5-ounce increments most closely approximating the Reference Amount with rounding indicated by the use of the term "about" (e.g., about 2.5 ounces).

(iv) A description of the individual container or package shall be used for single-serving containers and meal-type products and for individually packaged products within multi-serving containers (e.g., can, box, package, meal, or dinner). A description of the individual unit shall be used for other products in discrete units (e.g., wing, slice, link, or patty).

(v) For unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g., pizza kit), the fraction or portion of the package may be used.

(vi) For products that consist of two or more distinct ingredients or components packaged and presented to be consumed together (e.g., chicken wings with a glaze packet), the nutrition information may be declared for each component or as a composite. The serving size may be provided in accordance with the provisions of paragraphs (b)(4), (b)(5), and (b)(6) of this section.

(vii) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL), a tablespoon means 15 mL, a cup means 240 mL, and 1 oz in weight means 28 grams (g).

(viii) When a serving size, determined from the Reference Amount in § 381.412(b) and the procedures described in this section, falls exactly

half way between two serving sizes (e.g., 2.5 tbsp), manufacturers shall round the serving size up to the next incremental size.

(8) A product that is packaged and sold individually and that contains less than 200 percent of the applicable Reference Amount shall be considered to be a single-serving container, and the entire content of the product shall be labeled as one serving, except for products that have Reference Amounts of 100 g (or mL) or larger, manufacturers may decide whether a package that contains more than 150 percent but less than 200 percent of the Reference Amount is 1 or 2 servings. Packages sold individually that contain 200 percent or more of the applicable Reference Amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.

(9) A label statement regarding a serving shall be the serving size expressed in common household measures as set forth in paragraphs (b)(2) through (b)(8) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in milliliters and all other foods in grams), except for single-serving containers.

(i) For a single-serving container, the parenthetical metric quantity, which will be presented as part of the net weight statement on the principal display panel, is not required except where nutrition information is required on a drained weight basis according to paragraph (b)(11) of this section.

However, if a manufacturer voluntarily provides the metric quantity on products that can be sold as single servings, then the numerical value provided as part of the serving size declaration must be identical to the metric quantity declaration provided as part of the net quantity of contents statement.

(ii) The gram or milliliter quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g (mL). The gram (mL) quantity between 2 and 5 g (mL) should be rounded to the nearest 0.5 g (mL) and the g (mL) quantity less than 2 g (mL) should be expressed in 0.1-g (mL) increments.

(iii) In addition, serving size may be declared in ounce, in parenthesis, following the metric measure separated by a slash where other common household measures are used as the primary unit for serving size, e.g., 1 slice (28 g/1 oz) for sliced chicken roll. The ounce quantity equivalent to the metric quantity should be expressed in 0.1-oz increments.

(iv) If a manufacturer elects to use abbreviations for units, the following abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, and oz for ounce.

(10) Determination of the number of servings per container shall be based on the serving size of the product determined by following the procedures described in this section.

(i) The number of servings shall be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings shall be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term "about" (e.g., about 2 servings; about 3.5 servings).

(ii) When the serving size is required to be expressed on a drained solids basis and the number of servings varies because of a natural variation in unit size, the manufacturer may state the typical number of servings per container (e.g., usually 5 servings).

(iii) For random weight products, a manufacturer may declare "varied" for the number of servings per container provided the nutrition information is based on the Reference Amount expressed in ounces. The manufacturer may provide the typical number of servings in parenthesis following the "varied" statement (e.g., varied (approximately 8 servings per pound)).

(iv) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the number of servings shall be the number of individual packages within the total package.

(v) For packages containing several individually packaged multi-serving units, the number of servings shall be determined by multiplying the number of individual multi-serving units in the total package by the number of servings in each individual unit.

(11) The declaration of nutrient and food component content shall be on the basis of product as packaged or purchased with the exception of products that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed. Declaration of the nutrient and food component content of products that are packed in liquid which is not customarily consumed shall be based on the drained solids.

(12) Serving size for meal-type products as defined in § 381.413(l) shall

be the entire content (edible portion only) of the package.

(13) Another column of figures may be used to declare the nutrient and food component information in the same format as required by § 381.409(e).

(i) Per 100 grams, 100 milliliters, or 1 ounce of the product as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit.

(14) If a product consists of assortments of poultry products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(15) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk): *Provided*, that the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(c) The declaration of nutrition information on the label or in labeling of a poultry product shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraph (f) or (g) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraph (d) or (e) of this section.

(1) "Calories, total," "Total calories," or "Calories": A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parenthesis immediately following the statement of the caloric content.

(i) Caloric content may be calculated by the following methods. Where either specific or general food factors are used, the factors shall be applied to the actual amount (i.e., before rounding) of food components (e.g., fat, carbohydrate, protein, or ingredients with specific food factors) present per serving.

(A) Using specific Atwater factors (i.e., the Atwater method) given in Table 13, page 25, "Energy Value of Foods—Basis and Derivation," by A. L. Merrill and B. K. Watt, United States Department of Agriculture (USDA), Agriculture Handbook No. 74 (Slightly revised February 1973), which is incorporated by reference. Table 13 of the "Energy Value of Foods—Basis and Derivation," Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the Office of the Federal Register, suite 700, 800 North Capitol Street, NW., Washington, DC, or at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC. Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250-3700;

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9-11, which is incorporated by reference. Pages 9-11, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.);

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9-11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.); or

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in

parts 172 or 184 of 21 CFR, or by other means, as appropriate.

(ii) "Calories from fat": A statement of the caloric content derived from total fat as defined in paragraph (c)(2) of this section per serving, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that label declaration of "calories from fat" is not required on products that contain less than 0.5 gram of fat per serving and amounts less than 5 calories may be expressed as zero. This statement shall be declared as provided in paragraph (d)(5) of this section.

(iii) "Calories from saturated fat" or "Calories from saturated" (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section per serving may be declared voluntarily, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories from fat as provided in paragraph (d)(5) of this section.

(2) "Fat, total" or "Total fat": A statement of the number of grams of total fat per serving defined as total lipid fatty acids and expressed as triglycerides. Amounts shall be expressed to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(i) "Saturated fat" or "Saturated": A statement of the number of grams of saturated fat per serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat per serving if no claims are made about fat or cholesterol content, and if "calories from saturated fat" is not declared. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(A) "Stearic Acid" (VOLUNTARY): A statement of the number of grams of stearic acid per serving may be declared voluntarily, except that when a claim is made about stearic acid, label declaration shall be required. Stearic acid content shall be indented under saturated fat and expressed to the

nearest 0.5 (1/2)-gram increment below 5 grams and the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(B) [Reserved]

(ii) "Polyunsaturated fat" or "Polyunsaturated" (VOLUNTARY): A statement of the number of grams of polyunsaturated fat per serving defined as *cis,cis*-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 381.462(b)(1) for a claim for "fat free," label declaration of polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iii) "Monounsaturated fat" or "Monounsaturated" (VOLUNTARY): A statement of the number of grams of monounsaturated fat per serving defined as *cis*-monounsaturated fatty acids may be declared voluntarily, except that when polyunsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 381.462(b)(1) for a claim for "fat free," label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(3) "Cholesterol": A statement of the cholesterol content per serving expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams of cholesterol per serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. If the product contains 2 to 5 milligrams of cholesterol per serving, the content may be stated as "less than 5 milligrams."

(4) "Sodium": A statement of the number of milligrams of sodium per serving expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving contains 5

to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(5) "Potassium" (VOLUNTARY): A statement of the number of milligrams of potassium per serving may be declared voluntarily, except that when a claim is made about potassium content, label declaration shall be required. Potassium content shall be expressed as zero when the serving contains less than 5 milligrams of potassium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of potassium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(6) "Carbohydrate, total" or "Total carbohydrate": A statement of the number of grams of total carbohydrate per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, or, if the serving contains less than 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the product. This calculation method is described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 2 and 3, which is incorporated by reference. Pages 2 and 3, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.)

(i) "Dietary fiber": A statement of the number of grams of total dietary fiber per serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required, or, alternatively, the statement "Contains less than 1 gram" or "less than 1 gram" may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(A) "Soluble fiber" (VOLUNTARY): A statement of the number of grams of soluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains

less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(B) "Insoluble fiber" (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) "Sugars": A statement of the number of grams of sugars per serving, except that label declaration of sugars content is not required for products that contain less than 1 gram of sugars per serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) "Sugar alcohol" (VOLUNTARY): A statement of the number of grams of sugar alcohols per serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the product, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol or xylitol) or is generally recognized as safe (e.g., sorbitol). In lieu of the term "sugar alcohol," the name of the specific sugar alcohol (e.g., "xylitol") present in the product may be used in the nutrition label, provided that only one sugar alcohol is present in the product. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iv) "Other carbohydrate" (VOLUNTARY): A statement of the number of grams of other carbohydrate per serving may be declared voluntarily. Other carbohydrate shall be defined as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present), it shall be defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. Other carbohydrate content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) "Protein": A statement of the number of grams of protein per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in products represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a product represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement "not a significant source of protein," or a listing aligned under the column headed "Percent Daily Value" of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as percent of Daily Value. When the protein quality in a product as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a product represented or purported to be for infants, the statement "not a significant source of protein" shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by appropriate methods of analysis in

accordance with § 381.409(h), except when the procedure for a specific food requires another factor.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be for infants or children under 4 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein and aligned under the column headed "Percent Daily Value," and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the product is represented or purported to be for infants and the protein quality value is less than 40 percent of the reference standard.

(ii) The corrected amount of protein (grams) per serving for products represented or purported to be for adults and children 1 or more years of age is equal to the actual amount of protein (grams) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8 in "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990, which is incorporated by reference. Sections 5.4.1, 7.2.1, and 8 of the "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," as published by the Food and Agriculture Organization of the United Nations/World Health Organization, is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the Office of the Federal Register, suite 700, 800 North Capitol Street, NW., Washington, DC, or at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC. Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250-3700. For products represented or purported

to be for infants, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject product's protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, and the RDI for protein for children less than 4 years of age, infants, pregnant women, and lactating women shall be 16 grams, 14 grams, 60 grams, and 65 grams, respectively.

(8) Vitamins and minerals: A statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a percent of the RDI and expressed as percent of Daily Value.

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d) through (g) of this section, products represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women shall use the RDI's that are specified for the intended group. For products represented or purported to be for use by both infants and children under 4 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants from birth to 12 months of age and for children under 4 years of age. Similarly, the percent of Daily Value based on both the RDI values for pregnant women and for lactating women shall be declared separately on products represented or purported to be for use by both pregnant and lactating women. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. All other products shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a percent of the RDI shall include vitamin A, vitamin C, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added, or when a claim is made about them. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or in labeling or advertising and the vitamins and minerals are:

(A) Required or permitted in a standardized food (e.g., thiamin, riboflavin, and niacin in enriched flour) and that standardized food is included as an ingredient (i.e., component) in another product; or

(B) Included in a product solely for technological purposes and declared only in the ingredients statement. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(8)(iv) of this section.

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, if vitamin A, vitamin C, calcium, or iron is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement "Not a significant source of \_\_\_\_\_ (listing the vitamins or minerals omitted)" is placed at the bottom of the table of nutrient values.

(iv) The following RDI's and nomenclature are established for the following vitamins and minerals which are essential in human nutrition:

- Vitamin A, 5,000 International Units
- Vitamin C, 60 milligrams
- Calcium, 1.0 gram
- Iron, 18 milligrams
- Vitamin D, 400 International Units
- Vitamin E, 30 International Units
- Thiamin, 1.5 milligrams
- Riboflavin, 1.7 milligrams
- Niacin, 20 milligrams
- Vitamin B<sub>6</sub>, 2.0 milligrams
- Folate, 0.4 milligram
- Vitamin B<sub>12</sub>, 6 micrograms
- Biotin, 0.3 milligram
- Pantothenic acid, 10 milligrams
- Phosphorus, 1.0 gram
- Iodine, 150 micrograms
- Magnesium, 400 milligrams
- Zinc, 15 milligrams
- Copper, 2.0 milligrams

(v) The following synonyms may be added in parenthesis immediately

following the name of the nutrient or dietary component:

- Vitamin C—Ascorbic acid
- Thiamin—Vitamin B<sub>1</sub>
- Riboflavin—Vitamin B<sub>2</sub>
- Folate—Folacin
- Calories—Energy

(vi) A statement of the percent of vitamin A that is present as *beta*-carotene may be declared voluntarily. When the vitamins and minerals are listed in a single column, the statement shall be indented under the information on vitamin A. When vitamins and minerals are arrayed horizontally, the statement of percent shall be presented in parenthesis following the declaration of vitamin A and the percent of Daily Value of vitamin A in the product (e.g., "Percent Daily Value: Vitamin A 50 (90 percent as *beta*-carotene)"). When declared, the percentages shall be expressed in the same increments as are provided for vitamins and minerals in paragraph (c)(8)(iii) of this section.

(9) For the purpose of labeling with a percent of the DRV, the following DRV's are established for the following food components based on the reference caloric intake of 2,000 calories:

Food component	Unit of measurement	DRV
Fat .....	grams (g) .....	65
Saturated fatty acids .....	.....do .....	20
Cholesterol .....	milligrams (mg) ..	300
Total carbohydrate .....	grams (g) .....	300
Fiber .....	.....do .....	25
Sodium .....	milligrams (mg) ..	2400
Potassium .....	.....do .....	3500
Protein .....	grams (g) .....	50

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on products in the following format, except on products on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those products on which the simplified format is permitted to be used as provided for in paragraph (f) of this section, on products for infants and children less than 4 years of age as provided for in § 381.500(c), and on products in packages that have a total surface area available to bear labeling of 40 or less square inches as provided for in paragraph (g) of this section.

(i) The nutrition information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the nutrition label shall utilize:

(A) A single easy-to-read type style,

(B) Upper and lower case letters,

(C) At least one point leading (i.e., space between two lines of text) except that at least two points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section, and

(D) Letters should never touch.

(iii) Information required in paragraphs (d)(3), (d)(5), (d)(7), and (d)(8) of this section shall be in type size no smaller than 8 point. Except for the heading "Nutrition Facts," the information required in paragraphs (d)(4), (d)(6), and (d)(9) of this section and all other information contained within the nutrition label shall be in type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall also be in type no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(4), and (d)(6) of this section (i.e., "Nutrition Facts," "Amount Per Serving," and "% Daily Value\*"), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (i.e., Calories, Total fat, Cholesterol, Sodium, Potassium, Total carbohydrate, and Protein), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted by bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate "Amount Per Serving" from the calorie statements required in paragraph (d)(5) of this section and shall separate each nutrient and its corresponding percent of Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent of Daily Value above and below it.

(2) The information shall be presented under the identifying heading of "Nutrition Facts" which shall be set in a type size larger than all other print size in the nutrition label and, except for labels presented according to the format provided for in paragraph (d)(11) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section.

(3) Information on serving size shall immediately follow the heading. Such information shall include:

(i) "Serving Size": A statement of the serving size as specified in paragraph (b)(9) of this section.

(ii) "Servings Per Container": The number of servings per container, except that this statement is not required on single-serving containers as defined in paragraph (b)(8) of this section.

(4) A subheading "Amount Per Serving" shall be separated from serving size information by a bar.

(5) Information on calories shall immediately follow the heading "Amount Per Serving" and shall be declared in one line, leaving sufficient space between the declaration of "Calories" and "Calories from fat" to allow clear differentiation, or, if "Calories from saturated fat" is declared, in a column with total "Calories" at the top, followed by "Calories from fat" (indented), and "Calories from saturated fat" (indented).

(6) The column heading "% Daily Value," followed by an asterisk (e.g., "% Daily Value\*"), shall be separated from information on calories by a bar. The position of this column heading shall allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the left of, and below, this column heading. The column heading "Percent Daily Value," "Percent DV," or "% DV" may be substituted for "% Daily Value."

(7) Except as provided for in paragraph (g) of this section, and except as permitted by § 381.500(d)(2), nutrient information for both mandatory and any voluntary nutrients listed in paragraph (c) of this section that are to be declared in the nutrition label, except vitamins and minerals, shall be declared as follows:

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a "g" for grams or "mg" for milligrams.

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading "% Daily Value" established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The

percent shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (i.e., %).

(8) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed horizontally (e.g., Vitamin A 4%, Vitamin C 2%, Calcium 15%, Iron 4%) or may be listed in two columns, except that when more than four vitamins and minerals are declared, they may be declared vertically with percentages listed under the column headed "% Daily Value."

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from that list by a hairline.

(i) The footnote shall state: Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories	2,000	2,500
Total fat .	Less than .	65 g	80 g
Saturated fat.	Less than .	20 g	25 g
Cholesterol.	Less than .	300 mg	300 mg
Sodium ..	Less than .	2400 mg	2400 mg
Total carbohydrate.	.....	300 g	375 g
Dietary fiber.	.....	25 g	30 g

(ii) If the percent of Daily Value is given for protein in the Percent of Daily Value column as provided in paragraph (d)(7)(ii) of this section, protein shall be listed under dietary fiber, and a value of 50 g shall be inserted on the same line in the column headed "2,000" and value of 65 g in the column headed "2,500."

(iii) If potassium is declared in the column described in paragraph (d)(7)(i) of this section, potassium shall be listed under sodium and the DRV established in paragraph (c)(9) of this section shall be inserted on the same line in the numeric columns.

(iv) The abbreviations established in paragraph (g)(2) of this section may be used within the footnote.

(10) Caloric conversion information on a per-gram basis for fat, carbohydrate, and protein may be presented beneath the information required in paragraph (d)(9), separated from that information by a hairline. This information may be presented horizontally (i.e., "Calories per gram: Fat 9, Carbohydrate 4, Protein 4") or vertically in columns.

(11)(i) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in paragraph (d)(9) of this section, the information required in paragraph (d)(9) may be moved to the right of the column required in paragraph (d)(7)(ii) of this section and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(ii) If the space beneath the mandatory declaration of iron is not adequate to accommodate any remaining vitamins and minerals to be declared or the information required in paragraph (d)(9) of this section, the remaining information may be moved to the right and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information given to the left. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(iii) If there is not sufficient continuous vertical space (i.e., approximately 3 inches) to accommodate the required components of the nutrition label up to and including the mandatory declaration of iron, the nutrition label may be presented in a tabular display in which the footnote required by paragraph (d)(9) of the section is given to the far right of the label, and additional vitamins and minerals beyond the four that are required (i.e., vitamin A, vitamin C, calcium, and iron) are arrayed horizontally following declarations of the required vitamins and minerals.

(12) The following sample label illustrates the provisions of paragraph (d) of this section:

BILLING CODE 3410-DM-P

# Nutrition Facts

Serving Size 1 cup (228g)  
Servings Per Container 2

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**Amount Per Serving**

**Calories 260**    Calories from Fat 120

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	<b>% Daily Value*</b>
<b>Total Fat</b> 13g	<b>20%</b>
Saturated Fat 5g	<b>25%</b>
<b>Cholesterol</b> 30mg	<b>10%</b>
<b>Sodium</b> 660mg	<b>28%</b>
<b>Total Carbohydrate</b> 31g	<b>10%</b>
Dietary Fiber 0g	<b>0%</b>
Sugars 5g	
<b>Protein</b> 5g	

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Vitamin A 4%	•	Vitamin C 2%
Calcium 15%	•	Iron 4%

---

\* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

		Calories: 2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

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Calories per gram:  
Fat 9 • Carbohydrate 4 • Protein 4

(13)(i) Nutrition labeling on the outer label of packages of poultry products that contain two or more products in the same packages (e.g., variety packs) or of packages that are used interchangeably for the same type of food (e.g., poultry salad containers) may use an aggregate display.

(ii) Aggregate displays shall comply with format requirements of paragraph (d) of this section to the maximum extent possible, except that the identity of each food shall be specified to the right of the "Nutrition Facts" title, and both the quantitative amount by weight (i.e., g/mg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food.

(14) When nutrition labeling appears in a second language, the nutrition information may be presented in a separate nutrition label for each language or in one nutrition label with the information in the second language following that in English. Numeric characters that are identical in both languages need not be repeated (e.g., "Protein/Proteinas 2 g"). All required information must be included in both languages.

(e) Nutrition information may be presented for two or more forms of the same product (e.g., both "raw" and "cooked") or for common combinations of foods as provided for in paragraph (b) of this section, or for different units (e.g., per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDI's are established (e.g., both infants and children less than 4 years of age) as provided for in paragraph (c)(8)(i) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information

shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the subheading of "Amount Per Serving," there shall be two or more column headings accurately describing the forms of the same product (e.g., "raw" and "roasted"), the combinations of foods, the units, or the RDI groups that are being declared. The column representing the product as packaged and according to the label serving size based on the Reference Amount in § 381.412(b) shall be to the left of the numeric columns.

(2) When the dual labeling is presented for two or more forms of the same product, for combinations of foods, or for different units, total calories and calories from fat (and calories from saturated fat, when declared) shall be listed in a column and indented as specified in paragraph (d)(5) of this section with quantitative amounts declared in columns aligned under the column headings set forth in paragraph (e)(1) of this section.

(3) Quantitative information by weight required in paragraph (d)(7)(i) of this section shall be specified for the form of the product as packaged and according to the label serving size based on the Reference Amount in § 381.412(b).

(i) Quantitative information by weight may be included for other forms of the product represented by the additional column(s) either immediately adjacent to the required quantitative information by weight for the product as packaged and according to the label serving size based on the Reference Amount in § 381.412(b) or as a footnote.

(A) If such additional quantitative information is given immediately adjacent to the required quantitative

information, it shall be declared for all nutrients listed and placed immediately following and differentiated from the required quantitative information (e.g., separated by a comma). Such information shall not be put in a separate column.

(B) If such additional quantitative information is given in a footnote, it shall be declared in the same order as the nutrients are listed in the nutrition label. The additional quantitative information may state the total nutrient content of the product identified in the second column or the nutrient amounts added to the product as packaged for only those nutrients that are present in different amounts than the amounts declared in the required quantitative information. The footnote shall clearly identify which amounts are declared. Any subcomponents declared shall be listed parenthetically after principal components (e.g., 1/2 cup skim milk contributes an additional 40 calories, 65 mg sodium, 6 g total carbohydrate (6 g sugars), and 4 g protein).

(ii) Total fat and its quantitative amount by weight shall be followed by an asterisk (or other symbol) (e.g., "Total fat (2 g)\*") referring to another asterisk (or symbol) at the bottom of the nutrition label identifying the form(s) of the product for which quantitative information is presented.

(4) Information required in paragraphs (d)(7)(ii) and (d)(8) of this section shall be presented under the subheading "% DAILY VALUE" and in columns directly under the column headings set forth in paragraph (e)(1) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

BILLING CODE 3410-DM-P

<b>Nutrition Facts</b>		
Serving Size $\frac{1}{12}$ package (44g, about $\frac{1}{4}$ cup dry mix)		
Servings Per Container 12		
Amount Per Serving	Mix	Baked
<b>Calories</b>	190	280
Calories from Fat	45	140
% Daily Value**		
<b>Total Fat 5g*</b>	<b>8%</b>	<b>24%</b>
Saturated Fat 2g	10%	13%
<b>Cholesterol 0mg</b>	<b>0%</b>	<b>23%</b>
<b>Sodium 300mg</b>	<b>13%</b>	<b>13%</b>
<b>Total Carbohydrate 34g</b>	<b>11%</b>	<b>11%</b>
Dietary Fiber 0g	0%	0%
Sugars 18g		
<b>Protein 2g</b>		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%
* Amount in Mix		
** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:		
	Calories:	2,000    2,500
Total Fat	Less than	65g    80g
Sat Fat	Less than	20g    25g
Cholesterol	Less than	300mg    300mg
Sodium	Less than	2,400mg    2,400mg
Total Carbohydrate		300g    375g
Dietary Fiber		25g    30g
Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4		

BILLING CODE 3410-DM-C

(f)(1) Nutrition information may be presented in a simplified format as set forth herein when any required nutrients, other than the core nutrients (i.e., calories, total fat, sodium, total carbohydrate, and protein), are present in insignificant amounts. An insignificant amount shall be defined as that amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, sugars and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include information on the following nutrients:

- (i) Total calories, total fat, total carbohydrate, sodium, and protein;
- (ii) Any of the following that are present in more than insignificant amounts: Calories from fat, saturated fat, cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron; and
- (iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section

when they are added in fortified or fabricated foods.

(3) Other nutrients that are naturally present in the product in more than insignificant amounts may be voluntarily declared as part of the simplified format.

(4) Any required nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the tabular listing, provided that the following statement is included at the bottom of the nutrition label, "Not a significant source of \_\_\_\_\_." The

blank shall be filled in with the appropriate nutrient or food component. Alternatively, amounts of vitamins and minerals present in insignificant amounts may be declared by the use of an asterisk (or symbol) that is placed at the bottom of the table of nutrient values and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)."

(5) Except as provided for in paragraph (g) of this section and in § 381.500(c) and (d), nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote required in paragraph (d)(9) of this section is not required. When the footnote is omitted, an asterisk shall be placed at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value."

(g) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (c) through (f) of this section and § 381.402(a) by one or more of the following means:

(1)(i) Presenting the required nutrition information in a tabular or linear (i.e., string) fashion, rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches, or if the product has a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Nutrition information may be given in a linear fashion only if the package shape or size will not accommodate a tabular display.

(ii) When nutrition information is given in a linear display, the nutrition information shall be set off in a box by the use of a hairline. The percent Daily Value is separated from the quantitative amount declaration by the use of parenthesis, and all nutrients, both principal components and subcomponents, are treated similarly. Bolding is required only on the title "Nutrition Facts" and is allowed for nutrient names for "Calories," "Total fat," "Cholesterol," "Sodium," "Total carbohydrate," and "Protein."

(2) Using any of the following abbreviations:

Serving size—Serv size

Servings per container—Servings

Calories from fat—Fat cal

Calories from saturated fat—Sat fat cal  
Saturated fat—Sat fat  
Monounsaturated fat—Monounsaturat fat  
Polyunsaturated fat—Polyunsaturat fat  
Cholesterol—Cholest  
Total carbohydrate—Total carb  
Dietary fiber—Fiber  
Soluble fiber—Sol fiber  
Insoluble fiber—Insol fiber  
Sugar alcohol—Sugar alc  
Other carbohydrate—Other carb

(3) Omitting the footnote required in paragraph (d)(9) of this section and placing another asterisk at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value."

\* \* \* \* \*

21. Section 381.412 is amended by redesignating paragraph (d) as (g), revising paragraph (a), and adding new paragraphs (d), (e), and (f) to read as follows: § 381.412 *Reference amounts customarily consumed per eating occasion.*

(a) The general principles followed in arriving at the reference amounts customarily consumed per eating occasion (Reference Amount(s)), as set forth in paragraph (b) of this section, are:

(1) The Reference Amounts are calculated for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These Reference Amounts are based on data set forth in appropriate national food consumption surveys.

(2) The Reference Amounts are calculated for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These Reference Amounts are based on data set forth in appropriate national food consumption surveys. Such Reference Amounts are to be used only when the product is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, the mean, median, and mode of the consumed amount per eating occasion were considered.

(5) When survey data were insufficient, FSIS took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the Reference Amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The Reference Amount is based on the major intended use of the product (e.g., a mixed dish measurable with a cup as a main dish and not as a side dish).

(8) The Reference Amounts for products that are consumed as an ingredient of other products, but that may also be consumed in the form in which they are purchased (e.g., ground poultry), are based on use in the form purchased.

(9) FSIS sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform Reference Amount.

\* \* \* \* \*

(d) If a product requires further preparation, e.g., cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a Reference Amount for the product in the prepared form, then the Reference Amount for the unprepared product shall be determined using the following rules:

(1) Except as provided for in paragraph (d)(2) of this section, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the Reference Amount for the prepared product as established in paragraph (b) of this section.

(2) For products where the entire contents of the package is used to prepare one large discrete unit usually divided for consumption, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the fraction of the large discrete unit closest to the Reference Amount for the prepared product as established in paragraph (b) of this section.

(e) The Reference Amount for an imitation or substitute product or altered product as defined in § 381.413(d), such as a "low calorie" version, shall be the same as for the product for which it is offered as a substitute.

(f) The Reference Amounts set forth in paragraphs (b) through (e) of this section shall be used in determining whether a product meets the criteria for nutritional claims. If the serving size declared on the product label differs from the Reference Amount, and the product meets the criteria for the claim only on the basis of the Reference Amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the Reference Amount as it appears in paragraph (b) of this section followed, in parenthesis, by the amount in common household measure if the Reference Amount is expressed in measures other than common household measures.

\* \* \* \* \*

22. Section 381.413 is amended by revising paragraphs (b), (g), (i), (j), (k), (p), and (q)(4) and adding new paragraphs (c), (d), (e), and (f) to read as follows:

**§ 381.413 Nutrient content claims; general principles.**

\* \* \* \* \*

(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 381.409, may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this subpart.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the product, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the product or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the product, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on products intended specifically for use

by infants and children less than 2 years of age unless the claim is specifically provided for in subpart Y of this part.

(4) Reasonable variations in the spelling of the terms defined in applicable provisions in this subpart and their synonyms are permitted provided these variations are not misleading (e.g., "hi" or "lo").

(c) Information that is required or permitted by § 381.409 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A "substitute" product is one that may be used interchangeably with another product that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an "imitation."

(1) If there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., "not recommended for frying").

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 381.121(c) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2).

(e)(1) Because the use of a "free" or "low" claim before the name of a product implies that the product differs from other products of the same type by virtue of its having a lower amount of the nutrient, only products that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the product, remove the nutrient from the product, or not include the nutrient in the product, may bear such a claim (e.g., "low sodium chicken noodle soup").

(2) Any claim for the absence of a nutrient in a product, or that a product is low in a nutrient when the product has not been specially processed, altered, formulated, or reformulated to

qualify for that claim shall indicate that the product inherently meets the criteria and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches (e.g., "chicken breast meat, a low sodium food").

(f) A nutrient content claim shall be in type size and style no larger than two times that of the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) Labeling information required in §§ 381.413, 381.454, 381.456, 381.460, 381.461, 381.462, and 381.480, whose type size is not otherwise specified, is required to be in letters and/or numbers no less than 1/16 inch in height, except as permitted by § 381.500(d)(2).

(h) [Reserved]

(i) Except as provided in § 381.409 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is consistent with a definition for a claim, as provided in subpart Y of this part, for the nutrient that the label addresses. Such a claim might be, "less than 10 g of fat per serving;"

(2) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the product is not "low" in or a "good source" of the nutrient, such as "only 200 milligrams (mg) sodium per serving, not a low sodium product." The disclaimer must be in easily legible print or type and in a size no less than required by § 381.121(c) for the net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2);

(3) The statement does not in any way implicitly characterize the level of the nutrient in the product and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

(4) "Percent fat free" claims are not authorized by this paragraph. Such claims shall comply with § 381.462(b)(6).

(j) A product may bear a statement that compares the level of a nutrient in the product with the level of a nutrient

in a reference product. These statements shall be known as "relative claims" and include "light," "reduced," "less" (or "fewer"), and "more" claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the product must be compared to an amount of nutrient in an appropriate reference product as specified in this paragraph (j).

(i)(A) For "less" (or "fewer") and "more" claims, the reference product may be a dissimilar product within a product category that can generally be substituted for one another in the diet or a similar product.

(B) For "light," "reduced," and "added" claims, the reference product shall be a similar product, and

(ii)(A) For "light" claims, the reference product shall be representative of the type of product that includes the product that bears the claim. The nutrient value for the reference product shall be representative of a broad base of products of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the product type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than "light," including "less" and "more" claims, the reference product may be the same as that provided for "light" in paragraph (j)(1)(ii)(A) of this section or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name, provided the name of the competitor is not used on the labeling of the product. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either the values declared in nutrition labeling or the actual nutrient values, provided that the resulting labeling is internally consistent (i.e., that the values stated in the nutrition information, the nutrient values in the accompanying information, and the declaration of the percentage of nutrient by which the product has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to

the percentage specified in the definition of the claim.

(2) For products bearing relative claims:

(i) The label or labeling must state the identity of the reference product and the percent (or fraction) of the amount of the nutrient in the reference product by which the nutrient has been modified, (e.g., "50 percent less fat than 'reference product'" or "1/3 fewer calories than 'reference product'"); and

(ii) This information shall be immediately adjacent to the most prominent claim in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 381.121(c) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim, but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2).

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving size with that in the reference product; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition information.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the requirement for a "low" claim for that nutrient.

(k) The term "modified" may be used in the statement of identity of a product that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., "modified fat 'product'"). This statement of identity must be immediately followed by the comparative statement such as "contains 35 percent less fat than 'reference product'." The label or

labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

\* \* \* \* \*

(p)(1) Unless otherwise specified, the reference amount customarily consumed set forth in § 381.412(b) through (e) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 381.412(f) (e.g., "very low sodium, 35 mg or less per 55 grams").

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size that is no less than that required by § 381.121(c) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the criteria statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2).

(q) \* \* \*

(4) The requirements of this section do not apply to infant formulas and medical foods, as described in 21 CFR 101.13(q)(4).

\* \* \* \* \*

22. Section 381.445 is amended by revising the section reference in paragraph (c) from "§ 381.409(g)" to "§ 381.409(f)" and by revising paragraph (a)(2) introductory text, (a)(2)(ii) and (a)(2)(iii) to read as follows: *§ 381.445 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.*

(a) \* \* \*

(2) A retailer may choose to provide nutrition information at the point-of-purchase, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials all of the requirements of the mandatory nutrition labeling program apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials:

(i) \* \* \*

(ii) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in § 381.409(c)(8)) and footnote required by § 381.409(d)(9) may be omitted; and

(iii) The point-of-purchase materials are not subject to any of the format requirements.

\* \* \* \* \*

23. Section 381.454 is revised to read as follows:

**§ 381.454 Nutrient content claims for "good source," "high," and "more."**

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a product in relation to the Reference Daily Intake (RDI) or Daily Reference Value (DRV), established for that nutrient (excluding total carbohydrate) in § 381.409(c), may only be made on the label or in labeling of the product 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 § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *"High" claims.* (1) The terms "high," "rich in," or "excellent source of" may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that the product 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 or in labeling of a meal-type product as defined in § 381.413(l), 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 meal is high in vitamin C").

(c) *"Good Source" claims.* (1) The terms "good source," "contains," or "provides" may be used on the label or in labeling of products, except meal-type products as described in § 381.413(l), provided that the product 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 or in labeling of a meal-type product as defined in § 381.413(l), 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 meal 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, i.e., that the product is high in fiber, a good source of fiber, or that the product contains "more" fiber, and the product is not "low" in total fat as defined in § 381.462(b)(2) or, in the case of a meal-type product, is not "low" in total fat as defined in § 381.462(b)(3), then the labeling shall disclose the level of total fat per labeled serving size (e.g., "contains 12 grams (g) of fat per serving"); and

(2) The disclosure shall appear in immediate proximity to such claim and be in a type size no less than one-half the size of the claim.

(e) *"More" claims.* (1) A relative claim using the terms "more" and "added" may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a product, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (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 'reference product'"); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "fiber content of 'reference product' is 1 g per serving; 'this product' contains 4 g per serving").

(2) A relative claim using the terms "more" and "added" may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (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 per 3 ounces (oz) than does 'reference product'"), and

(B) Quantitative information comparing the level of the nutrient in the meal-type product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "fiber content of 'reference product' is 2 g per 3 oz; 'this product' contains 5 g per 3 oz").

24. Section 381.456 is revised to read as follows:

**§ 381.456 Nutrient content claims for "light" or "lite."**

(a) *General requirements.* A claim using the terms "light" or "lite" to describe a product may only be made on the label or in labeling of the product 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 § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *"Light" claims.* The terms "light" or "lite" may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), without further qualification, provided that:

(1) If the product 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 product as described in § 381.413(j)(1); or

(2) If the product 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 product as described in § 381.413(j)(1); or

(ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the appropriate reference product as described in § 381.413(j)(1); and

(3) As required in § 381.413(j)(2) for relative claims:

(i) The identity of the reference product 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., “ $\frac{1}{3}$  fewer calories and 50 percent less fat than the market leader”); and

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “lite ‘this product’—200 calories, 4 grams (g) fat; regular ‘reference product’—300 calories, 8 g fat per serving”); and

(iii) If the labeled product 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 product for which the reference product meets the definition of “low fat” and “low calorie.”

(c)(1)(i) A product for which the reference product contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the terms “light” or “lite” without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference product; and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., “50 percent less sodium than the market leader”); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “lite ‘this product’—500 milligrams (mg) sodium per serving; regular ‘reference product’—1,000 mg sodium per serving”).

(2)(i) A product for which the reference product contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the terms “light in sodium” or “lite in sodium” if it is reduced by 50 percent or more in sodium content compared to the

reference product, 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 § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., “50 percent less sodium than the market leader”); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., or “lite ‘this product’—170 mg sodium per serving; regular ‘reference product’—350 mg per serving”).

(3) Except for meal-type products as defined in § 381.413(l), a “light in sodium” claim may not be made on a product for which the reference product meets the definition of “low in sodium.”

(d)(1) The terms “light” or “lite” may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product meets the definition of:

(A) “Low in calories” as defined in § 381.460(b)(3); or

(B) “Low in fat” as defined in § 381.462(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 terms “light in sodium” or “lite in sodium” may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that the product meets the definition of “low in sodium” as defined in § 381.461(b)(5)(i); and

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

(3) The terms “light” or “lite” may be used in the brand name of a product to describe the sodium content, provided that:

(i) The product is reduced by 50 percent or more in sodium content compared to the reference product;

(ii) A statement specifically stating that the product is “light in sodium” or “lite in sodium” appears:

(A) Contiguous to the brand name; and

(B) In uniform type size, style, color, and prominence as the product name; and

(iii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim; and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information.

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

(1) It describes some physical or organoleptic attribute of the product 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 product to reflect a physical or organoleptic attribute 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 product as described in § 381.413(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not “low in sodium” as defined in § 381.461(b)(4), the statement “not a low sodium food,” shall appear adjacent to the nutrition information and the information required to accompany a relative claim shall appear on the label or labeling as specified in § 381.413(j)(2).

25. Section 381.460 is revised to read as follows:

**§ 381.460 Nutrient content claims for calorie content.**

(a) *General requirements.* A claim about the calorie or sugar content of a product may only be made on the label or in labeling of the product 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 § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *Calorie content claims.* (1) The terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietarily insignificant source of calories" may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 calories per reference amount customarily consumed and per labeled serving size; and

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

(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 products, except meal-type products as defined in § 381.413(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and does not provide more than 40 calories per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and does not provide more than 40 calories per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the "as prepared" form).

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

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type

product as defined in § 381.413(l), provided that:

(i) The product contains 120 calories or less 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 calorie content, it is labeled to clearly refer to all products 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 labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., lower calorie 'product'—"33 1/3 percent fewer calories than our regular 'product'"); and

(B) Quantitative information comparing the level of calories in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "calorie content has been reduced from 150 to 100 calories per serving").

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of products if the reference product 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 labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent fewer calories per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., "calorie reduced 'product', 25% less calories per ounce (oz) (or 3 oz) than our regular 'product'"); and

(B) Quantitative information comparing the level of calories in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "calorie content has been reduced from 110 calories per 3 oz to 80 calories per 3 oz").

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of products if the reference product meets the definition for "low calorie."

(c) *Sugar content claims.* (1) 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" may reasonably be expected to be regarded by consumers as terms that represent that the product 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 product may not be labeled with such terms unless:

(i) The product contains less than 0.5 g of sugars, as defined in § 381.409(c)(6)(ii), per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 0.5 g of sugars per labeled serving size;

(ii) The product 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 ingredients 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

(B) Such term is immediately accompanied, each time it is used, by either the statement "not a reduced calorie product," "not a low calorie product," 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 § 381.409(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging;

(ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice;

(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 product, and a functionally insignificant increase in sugars results;

(iv) The product that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement that the product is not "low calorie" or "calorie reduced" (unless the product meets the requirements for a "low" or "reduced calorie" product) 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 product, including products intended specifically for infants and children less than 2 years of age, is unsweetened or contains no added sweeteners in the case of a product that contains apparent substantial inherent sugar content, e.g., juices.

(4) 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 products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less sugars per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., "this product contains 25 percent less sugar than our regular product"); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "sugar content has been lowered from 8 g to 6 g per serving").

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less sugars per 100 g of product

than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced sugar 'product'—25% less sugar than our regular 'product'"); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz").

26. Section 381.461 is revised to read as follows:

**§ 381.461 Nutrient content claims for the sodium content.**

(a) *General requirements.* A claim about the level of sodium in a product may only be made on the label or in labeling of the product 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 § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(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 "dietarily insignificant source of sodium" may be used on the label or in labeling of products, provided that:

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

(ii) The product contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium unless the listing of the ingredient in the ingredients 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) 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 products of its type and not merely to the particular brand to which the label attaches.

(2) The terms "very low sodium" or "very low in sodium" may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and contains 35 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 35 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(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 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 products of its type and not merely to the particular brand to which the label attaches.

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 140 mg or less sodium per 100 g of product; 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 products 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 products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction)

that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced sodium 'product', 50 percent less sodium than regular 'product'"); and

(B) Quantitative information comparing the level of sodium in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "sodium content has been lowered from 300 to 150 mg per serving").

(iii) Claims described in paragraph (b)(6) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product 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 labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less sodium per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced sodium 'product'—30% less sodium per 3 oz than our 'regular product'"); and

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "sodium content has been reduced from 220 mg per 3 oz to 150 mg per 3 oz").

(iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in labeling of products if the nutrient content of the reference product 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 products only if the product 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 products only if:

(i) No salt is added during processing;

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

(iii) If the product is not sodium free, the statement "not a sodium free product" or "not for control of sodium in the diet" appears adjacent to the nutrition information of the product bearing the claim.

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

27. Section 381.462 is revised to read as follows:

**§ 381.462 Nutrient content claims for fat, fatty acids, and cholesterol content.**

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a product may only be made on the label or in labeling of products 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 § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *Fat content claims.* (1) The terms "fat free," "free of fat," "no fat," "zero fat," "without fat," "nonfat," "trivial source of fat," "negligible source of fat," or "dietarily insignificant source of fat" may be used on the label or in labeling of products, provided that:

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

(ii) The product 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 ingredients 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) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the

particular brand to which the label attaches.

(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 and in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

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

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the "as prepared" form).

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

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 3 g or less of total fat per 100 g of product 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 the fat content, it is labeled to clearly refer to all products 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 labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two

products are declared in immediate proximity to the most prominent such claim (e.g., "reduced fat—50 percent less fat than our regular 'product'"); and

(B) Quantitative information comparing the level of fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "fat content has been reduced from 8 g to 4 g per serving").

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product 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 labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less fat per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

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

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent such claim or to the nutrition information (e.g., "fat content has been reduced from 8 g per 3 oz to 5 g per 3 oz").

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

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

(i) The product 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 products 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.

(iv) A synonym for "\_\_\_\_\_ percent fat free" is "\_\_\_\_\_ percent lean."

(c) *Fatty acid content claims.* (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 labeling of products, provided that:

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

(ii) The product contains no ingredient that is generally understood by consumers to contain saturated fat unless the listing of the ingredient in the ingredients 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) 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 products of its type and not merely to the particular brand to which the label attaches.

(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 labeling of products, except meal-type products as defined in § 381.413(l), provided that:

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

(ii) If the product 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 products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (c)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 1 g or less of saturated fat 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 products 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 labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less saturated fat per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced saturated fat 'product', contains 50 percent less saturated fat than the national average for 'product'"); and

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "saturated fat reduced from 3 g to 1.5 g per serving").

(iii) Claims described in paragraph (c)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product 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 labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less saturated fat per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., "reduced saturated fat 'product', 50 percent less saturated fat than our regular 'product'"); and

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "saturated fat content

has been reduced from 2.5 g per 3 oz to 1.5 g per 3 oz”).

(iii) Claims described in paragraph (c)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product 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 labeling of products, provided that:

(i) The product contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product as defined in § 381.413(l), less than 2 mg of cholesterol per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredients 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”;

(iii) The product contains 2 g or less of saturated fat per reference amount customarily consumed or, in the case of a meal-type product as defined in § 381.413(l), 2 g or less of saturated fat per labeled serving size; and

(iv) If the product 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 products of its type and not merely to the particular brand to which it attaches; or

(v) If the product meets these conditions only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product 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 ‘product’, contains 100

percent less cholesterol than ‘reference product’”); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “contains no cholesterol compared with 30 mg in one serving of ‘reference product’”).

(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 labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i)(A) If the product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp:

(1) The product contains 20 mg or less of cholesterol per reference amount customarily consumed; and

(2) The product contains 2 g or less of saturated fat per reference amount customarily consumed; or

(B) If the product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less:

(1) The product contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the “as prepared” form); and

(2) The product contains 2 g or less of saturated fat per reference amount customarily consumed.

(ii) If the product 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 products of its type and not merely to the particular brand to which the label attaches; or

(iii) If the product contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product 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 ‘product’, contains 85 percent less cholesterol than our regular ‘product’”); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “cholesterol lowered from 30 mg to 5 mg per serving”).

(3) The terms defined in paragraph (d)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 20 mg or less of cholesterol per 100 g of product;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) If the product 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 products of its type and not merely to the particular brand to which the label attaches.

(4) The terms “reduced cholesterol,” “reduced in cholesterol,” “cholesterol reduced,” “less cholesterol,” “lower cholesterol,” or “lower in cholesterol” may be used on the label or in labeling of products or products that substitute for those products as specified in § 381.413(d), excluding meal-type products as defined in § 381.413(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per reference amount customarily consumed; and

(iii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product 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 ‘reference product’”); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “cholesterol lowered from 55 mg to 30 mg per serving”).

(iv) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product 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 labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product 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 than 'reference product'"); and

(B) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz).

(iv) Claims described in paragraph (d)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product 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 a product, provided that the product contains less than 10 g of fat, 4.5 g or less of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 381.413(l).

(2) The term "extra lean" may be used on the label or in labeling of a product, provided that the product contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 381.413(l).

28. Section 381.463 is amended by revising the section reference in paragraphs (b)(2) and (b)(3) from "§ 381.409(g)(1)" to "§ 381.409(f)(1)."

29. Section 381.469 is amended by removing the word "rule" from the third sentence of paragraph (m)(5).

30. Section 381.480 is amended by revising paragraphs (e) and (f) to read as follows:

**§ 381.480 Label statements relating to usefulness in reducing or maintaining body weight.**

\* \* \* \* \*

(e) "*Label terms suggesting usefulness as low calorie or reduced calorie foods*."

(1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, a product may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false or misleading, and the

product is labeled "low calorie" or "reduced calorie" or bears another comparative calorie claim in compliance with the applicable provisions in this subpart.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term "diet" that clearly shows that the product is offered solely for a dietary use other than regulating body weight, e.g., "for low sodium diets."

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other product that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) "Sugar free" and "no added sugar". Criteria for the use of the terms "sugar free" and "no added sugar" are provided for in § 381.460(c).

31. Section 381.500 is amended by removing the word "food" after the word "poultry" in paragraph (a) introductory text; by revising the words "Products produced" in paragraph (a)(1) introductory text to the words "Food products produced"; by revising the section reference in paragraph (c)(2)(iii) from "§ 381.409(e)" to "§ 381.409(d)(6)"; and by revising the words "at 21 CFR 101.9(d)(9)" in paragraph (c)(2)(v) to the words "in § 381.409(d)(9)".

Done at Washington, DC, on December 22, 1994.

**Michael R. Taylor,**

*Acting Under Secretary for Food Safety.*

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