[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2006]
[CITE: 21CFR101.9]

TITLE 21--FOOD AND DRUGS

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

SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION

PART 101 -- FOOD LABELING

Subpart A--General Provisions

Sec. 101.9 Nutrition labeling of food.

Food component	Unit of measurement	DRV
Fat	gram (g)	65

Fat..... gram (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

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

Food component	Unit of measurement	DRV
Fat.....	gram (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

	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

(a) Nutrition information relating to food shall be provided for all products intended for human consumption and offered for sale unless an exemption is provided for the product in paragraph (j) of this section.
(1) When food is in package form, the required nutrition labeling information shall appear on the label in the format specified in this section.
(2) When food is not in package form, the required nutrition labeling information shall be displayed clearly at the point of purchase (e.g., on a counter card, sign, tag affixed to the product, or some other appropriate device). Alternatively, the required information may be placed in a booklet, looseleaf binder, or other appropriate format that is available at the point of purchase.
(3) Solicitation of requests for nutrition information by a statement "For nutrition information write to _____ " on the label or in the labeling or advertising for a food, or providing such information in a direct written reply to a solicited or unsolicited request, does not subject the label or the labeling of a food exempted under paragraph (j) of this section to the requirements of this section if the reply to the request conforms to the requirements of this section.
(4) If any vitamin or mineral is added to a food so that a single serving provides 50 percent or more of the Reference Daily Intake (RDI) for the age group for which the product is intended, as specified in paragraph (c)(8)(iv) of this section, of any one of the added vitamins or minerals, unless such addition is permitted or required in other regulations, e.g., a standard of identity or nutritional quality guideline, or is otherwise exempted by the Commissioner, the food shall be considered a food for special dietary use within the meaning of 105.3(a)(1)(iii) of this chapter.
(b) Except as provided in 101.9(h)(3), all nutrient and food component quantities shall be declared in relation to a serving as defined in this section.
(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 food. When the food 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)(3), (b)(4), and (b)(6) 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

control or weight-maintenance program, serving size declared on a product label shall be determined from the "Reference Amounts Customarily Consumed Per Eating Occasion * * * *" (reference amounts) that appear in 101.12(b) using the procedures described below. 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 101.12(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrient content claims or health claims.

(i) For products in discrete units (e.g., muffins, sliced products, such as sliced bread, or individually packaged products within a multiserving 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., pancakes and syrup), the serving size shall be declared as follows:

(A) 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;

(B) 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;

(C) If a unit weighs 67 percent or more, but less than 200 percent of the reference amount, the serving size shall be one unit;

(D) 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.

(E) For products that have reference amounts of 100 grams (g) (or milliliter (mL)) or larger and are individual units within a multiserving 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.

(F) The serving size for maraschino cherries shall be expressed as 1 cherry with the parenthetical metric measure equal to the average weight of a medium size cherry.

(G) The serving size for products that naturally vary in size (e.g., pickles, shellfish, whole fish, and fillet of fish) may be the amount in ounces that most closely approximates the reference amount for the product category. Manufacturers shall adhere to the requirements in paragraph (b)(5)(vi) of this section for expressing the serving size in ounces.

(H) 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., pancakes and syrup), 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 determined in 101.12(f).

(I) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in 101.9 (that is, are labeled appropriately for individual sale as single-serving containers), the serving size shall be 1 unit.

(ii) For products in large discrete units that are usually divided for consumption (e.g., cake, pie, pizza, melon, cabbage), 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., cake mix, 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 (e.g., prepared cake packaged with a can of frosting), the serving size shall be the fractional slice of the ready-to-eat product (e.g., 1/12 cake, 1/8 pie, 1/4 pizza, 1/4 melon, 1/6 cabbage) that most closely approximates the reference amount for the product category, and may be the fraction of the package used to make the reference amount for the

and may be the fraction of the package used to make the reference amount for the unprepared product determined in 101.12(c) or the fraction of the large discrete unit represented as the main ingredient plus proportioned minor ingredients used to make the reference amount for the combined product determined in 101.12(f). In expressing the fractional slice, manufacturers shall use 1/2, 1/3, 1/4, 1/5, 1/6, or smaller fractions that can be generated by further division by 2 or 3.
(iii) For nondiscrete bulk products (e.g., breakfast cereal, flour, sugar, dry mixes, concentrates, pancake mixes, macaroni and cheese kits), 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., peanut butter and jelly), 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 101.12(f).
(3) The serving size for meal products and main dish products as defined in 101.13 (l) and (m) that comes in single-serving containers as defined in paragraph (b)(6) of this section shall be the entire content (edible portion only) of the package. Serving size for meal products and main dish products in multiserving containers shall be based on the reference amount applicable to the product in 101.12(b) if the product is listed in 101.12(b). Serving size for meal products and main dish products in multiserving containers that are not listed in 101.12(b) shall be based on the reference amount according to 101.12(f).
(4) A variety pack, such as a package containing several varieties of single-serving units as defined in paragraph (b)(2)(i) of this section, and a product having two or more compartments with each compartment containing a different food, shall provide nutrition information for each variety or food per serving size that is derived from the reference amount in 101.12(b) applicable for each variety or food and the procedures to convert the reference amount to serving size in paragraph (b)(2) of this section.
(5) For labeling purposes, the term *common household measure* or *common household unit* means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., 1/4 pizza), ounce (oz), fluid ounce (fl oz), or other common household equipment used to package food products (e.g., jar, tray). In expressing serving size in household measures, except as specified in paragraphs (b)(5)(iv), (b)(5)(v), (b)(5)(vi), and (b)(5)(vii) of this section, the following rules shall be used:
(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate except for beverages. For beverages, a manufacturer may use fluid ounces. Cups shall be expressed in 1/4- or 1/3-cup increments. Tablespoons shall be expressed as 1, 1 1/3, 1 1/2, 1 2/3, 2, or 3 tablespoons. Teaspoons shall be expressed as 1/8, 1/4, 1/2, 3/4, 1, or 2 teaspoons.
(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.
(iii) If paragraphs (b)(5)(i) and (b)(5)(ii) of this section are not applicable, ounces may be used with an appropriate visual unit of measure such as a dimension of a piece, e.g., 1 oz (28 g/about 1/2 pickle). Ounce measurements shall be expressed in 0.5 oz increments most closely approximating the reference amount.
(iv) A description of the individual container or package shall be used for single serving containers and for individually packaged products within multiserving containers (e.g., can, box, package). A description of the individual unit shall be used for other products in discrete units (e.g., piece, slice, cracker, bar).
(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., cake mix, pizza kit), the fraction or portion of the package may be used.
(vi) Ounces with an appropriate visual unit of measure, as described in paragraph (b)(5)(iii) of this section, may be used for products that naturally vary in size as provided for in paragraph (b)(2)(i)(G) of this section.

(vii) As provided for in 101.9(h)(1), for products that consist of two or more distinct ingredients or components packaged and presented to be consumed together (e.g. dry macaroni and cheese mix, cake and muffin mixes with separate ingredient packages, pancakes and syrup), 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)(2)(i), (b)(2)(ii), and (b)(2)(iii) of this section, or alternatively in ounces with an appropriate visual unit of measure, as described in paragraph (b)(5)(iii) of this section (e.g., declared as separate components: "3 oz dry macaroni (84 g/about 2/3 cup)" and "1 oz dry cheese mix (28 g/about 2 tbsp);" declared as a composite value: "4 oz (112 g/about 2/3 cup macaroni and 2 tbsp dry cheese mix)").
(viii) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL), a tablespoon means 15 mL, a cup means 240 mL, 1 fl oz means 30 mL, and 1 oz in weight means 28 g.
(ix) When a serving size, determined from the reference amount in 101.12(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.
(6) 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.
(7) 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)(6) 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 101.9(b)(9). 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 and fluid 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 bread. 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, oz for ounce, and fl oz for fluid ounce.
(v) For products that only require the addition of water or another ingredient that contains insignificant amounts of nutrients in the amount added and that are prepared in such a way that there are no significant changes to the nutrient profile, the amount of the finished product may be declared in parentheses at the end of the serving size declaration (e.g., 1/2 cup (120 mL) concentrated soup (makes 1 cup prepared)).
(vi) To promote uniformity in label serving sizes in household measures declared by different manufacturers, FDA has provided a guidance document entitled, "Guidelines for Determining the Gram Weight of the Household Measure." The guidance document can be obtained from the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-

obtained from the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.
(8) 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., maraschino cherries, pickles), 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.
(iv) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in 101.9 (that is, 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 multiserving units, the number of servings shall be determined by multiplying the number of individual multiserving units in the total package by the number of servings in each individual unit.
(9) The declaration of nutrient and food component content shall be on the basis of food as packaged or purchased with the exception of raw fish covered under 101.42 (see 101.44), packaged single-ingredient products that consist of fish or game meat as provided for in paragraph (j)(11) of this section, and of foods that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed (e.g., canned fish, maraschino cherries, pickled fruits, and pickled vegetables). Declaration of nutrient and food component content of raw fish shall follow the provisions in 101.45. Declaration of the nutrient and food component content of foods that are packed in liquid which is not customarily consumed shall be based on the drained solids.
(10) Another column of figures may be used to declare the nutrient and food component information:
(i) Per 100 g or 100 mL, or per 1 oz or 1 fl oz of the food as packaged or purchased;
(ii) Per one unit if the serving size of a product in discrete units in a multiserving container is more than 1 unit;
(iii) Per cup popped for popcorn in a multiserving container.
(11) If a product is promoted on the label, labeling, or advertising for a use that differs in quantity by twofold or greater from the use upon which the reference amount in 101.12(b) was based (e.g., liquid cream substitutes promoted for use with breakfast cereals), the manufacturer shall provide a second column of nutrition information based on the amount customarily consumed in the promoted use, in addition to the nutrition information per serving derived from the reference amount in 101.12(b), except that nondiscrete bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils), or traditionally used for multipurposes (e.g., eggs, butter, margarine), and multipurpose baking mixes are exempt from this requirement.
(c) The declaration of nutrition information on the label and in labeling of a food 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

as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraphs (f) or (j) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraphs (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 parentheses 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, "Energy Value of Foods--Basis and Derivation," by A. L. Merrill and B. K. Watt, United States Department of Agriculture (USDA) Handbook No. 74 (slightly revised, 1973), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and is available from the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be inspected at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*;
(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised 1973) pp. 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);
(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 Handbook No. 74 (slightly revised 1973) pp. 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;
(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 this chapter, or by other means, as appropriate; or
(E) Using bomb calorimetry data subtracting 1.25 calories per gram protein to correct for incomplete digestibility, as described in USDA Handbook No. 74 (slightly revised 1973) p. 10, 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).
(ii) "Calories from fat": A statement of the caloric content derived from total fat as defined in paragraph (c)(2) of this section in a 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 in a 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. Except as provided for in paragraph (f) of this section, if "Calories from fat" is not required and, as a result, not declared, the statement "Not a significant source of calories from fat" shall be placed at the bottom of the table of nutrient values in the same type size.
(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 in a 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

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 in a 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 in a 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 in a serving if no claims are made about fat, fatty acid, or cholesterol content, and if "calories from saturated fat" is not declared. Except as provided for in paragraph (f) of this section, if a statement of the saturated fat content is not required and, as a result, not declared, the statement "Not a significant source of saturated fat" shall be placed at the bottom of the table of nutrient values. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 gram (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.
(ii) "*Trans* fat" or "*Trans*": A statement of the number of grams of *trans* fat in a serving, defined as the sum of all unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration, except that label declaration of *trans* fat content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat, fatty acid or cholesterol content. The word "*trans*" may be italicized to indicate its Latin origin. *Trans* 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, when declared, shall be expressed as zero. Except as provided for in paragraph (f) of this section, if a statement of the *trans* fat content is not required and, as a result, not declared, the statement "Not a significant source of *trans* fat" shall be placed at the bottom of the table of nutrient values.
(iii) "Polyunsaturated fat" or "Polyunsaturated" (VOLUNTARY): A statement of the number of grams of polyunsaturated fat in a 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 food other than one that meets the criteria in 101.62(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.
(iv) "Monounsaturated fat" or "Monounsaturated" (VOLUNTARY): A statement of the number of grams of monounsaturated fat in a 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 food other than one that meets the criteria in 101.62(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 in a 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 cholesterol in a serving and make no claim about fat, fatty acids, or cholesterol

cholesterol in a serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. Except as provided for in paragraph (f) of this section, if cholesterol content is not required and, as a result, not declared, the statement "Not a significant source of cholesterol" shall be placed at the bottom of the table of nutrient values in the same type size. If the food 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 in a specified serving of food 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 in a specified serving of food 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 less than or equal to 140 milligrams of potassium, and to the nearest 10-milligram increment when the serving contains more than 140 milligrams.

(6) "Carbohydrate, total" or "Total carbohydrate": A statement of the number of grams of total carbohydrate in a 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 food. This calculation method is described in A. L. Merrill and B. K. Watt, "Energy Value of Foods--Basis and Derivation," USDA Handbook 74 (slightly revised 1973) pp. 2 and 3, 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).

(i) "Dietary fiber": A statement of the number of grams of total dietary fiber in a 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. Except as provided for in paragraph (f) of this section, if dietary fiber content is not required and as a result, not declared, the statement "Not a significant source of dietary fiber" shall be placed at the bottom of the table of nutrient values in the same type size.

(A) "Soluble fiber" (VOLUNTARY): A statement of the number of grams of soluble dietary fiber in a 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 in a serving may be declared voluntarily except that 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 in a serving, except that label declaration of sugars content is not required for products that contain less than 1 gram of sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Except as provided for in paragraph (f) of this section, if a statement

alcohol content. Except as provided for in paragraph (f) of this section, if a statement of the sugars content is not required and, as a result, not declared, the statement "Not a significant source of sugars" shall be placed at the bottom of the table of nutrient values in the same type size. 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 then 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 in a 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 food, 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 food may be used in the nutrition label provided that only one sugar alcohol is present in the food. 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 then 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 carbohydrates may be declared voluntarily. Other carbohydrates 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 in a 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 foods 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 food 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 food as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a food 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 the appropriate method of analysis as given in the "Official Methods of Analysis of the AOAC International" (formerly the Association of Official Analytical Chemists), 15th Ed. (1990), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, except when the official procedure for a specific food requires another factor. Copies may be obtained from AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500,

Copies may be obtained from AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be inspected at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(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 use by 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 food is represented or purported to be for use by infants and the protein quality value is less than 40 percent of the reference standard.

(ii) The "corrected amount of protein (gram) per serving" for foods represented or purported for adults and children 1 or more years of age is equal to the actual amount of protein (gram) 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 8.00 in "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990, except that when official AOAC procedures described in section (c)(7) of this paragraph require a specific food factor other than 6.25, that specific factor shall be used. 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 by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be inspected at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* For foods represented or purported 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 food 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 Daily Reference Value (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.

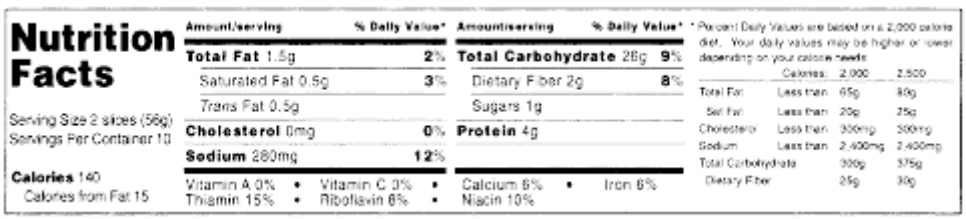
(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d), (e), and (f) of this section, foods represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women shall use the RDI's that are specified for the intended group. For foods 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 foods represented or purported to be for use by both pregnant and lactating women. When

foods 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 foods 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 as a nutrient supplement, 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 food; or
(B) Included in a food solely for technological purposes and declared only in the ingredient 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)" or "Contains < 2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, except as provided for in paragraph (f) of this section, 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. Either statement shall be in the same type size as nutrients that are indented.
(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, 1,000 milligrams
Iron, 18 milligrams
Vitamin D, 400 International Units
Vitamin E, 30 International Units
Vitamin K, 80 micrograms
Thiamin, 1.5 milligrams
Riboflavin, 1.7 milligrams
Niacin, 20 milligrams
Vitamin B6, 2.0 milligrams
Folate, 400 micrograms
Vitamin B12, 6 micrograms
Biotin, 300 micrograms
Pantothenic acid, 10 milligrams
Phosphorus, 1,000 milligrams
Iodine, 150 micrograms
Magnesium, 400 milligrams
Zinc, 15 milligrams
Selenium, 70 micrograms

Copper, 2.0 milligrams
Manganese, 2.0 milligrams
Chromium, 120 micrograms
Molybdenum, 75 micrograms
Chloride, 3,400 milligrams
(v) The following synonyms may be added in parentheses immediately following the name of the nutrient or dietary component:
Calories--Energy
Vitamin C--Ascorbic acid
Thiamin--Vitamin B1
Riboflavin--Vitamin B2
Folate--Folic acid or Folacin.
Alternatively, folic acid or folacin may be listed without parentheses in place of folate.
(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 DV of vitamin A in the food (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:
(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on foods in the following format, as shown in paragraph (d)(12) of this section, except on foods on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those food products on which the simplified format is required to be used as provided for in paragraph (f) of this section, on foods for infants and children less than 4 years of age as provided for in paragraph (j)(5) of this section, and on foods in small or intermediate-sized packages as provided for in paragraph (j)(13) of this section. In the interest of uniformity of presentation, FDA urges that the nutrition information be presented using the graphic specifications set forth in appendix B to part 101.
(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) Except as provided for in paragraph (c)(2)(ii) of this section, 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 as shown in paragraph (d)(12), 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," "Total Carbohydrate,"

section (i.e., "Calories," "Total Fat," "Cholesterol," "Sodium," "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 Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent Daily Value above and below it, as shown in paragraph (d)(12) of this section.
(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, as shown in paragraph (d)(12) of this section.
(3) Information on serving size shall immediately follow the heading as shown in paragraph (d)(12) of this section. Such information shall include:
(i) "Serving Size": A statement of the serving size as specified in paragraph (b)(7) 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)(6) of this section or on other food containers when this information is stated in the net quantity of contents declaration.
(4) A subheading "Amount Per Serving" shall be separated from serving size information by a bar as shown in paragraph (d)(12) of this section.
(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 as shown in paragraph (d)(12) of this section. 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 (j)(13) of this section, 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 a "mg" for milligrams as shown in paragraph (d)(12) of this section. The symbol "<" may be used in place of "less than."
(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., %).

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 as shown in paragraph (d)(12) of this section, 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.
(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 a 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 (j)(13)(ii)(B) 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) of this section, separated from that information by a hairline. This information may be presented horizontally as shown in paragraph (d)(12) of this section (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 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 nutrients and the percent DV 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 in) 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 as shown below.



View or download PDF

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

Nutrition Facts

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

Amount Per Serving

Calories 260	Calories from Fat 120
	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Trans Fat 2g	
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 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.

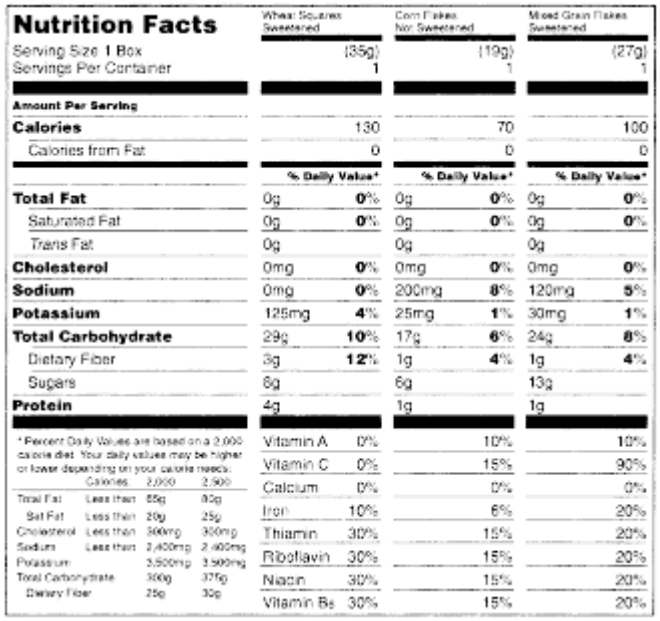
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

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

View or download PDF

(13)(i) Nutrition labels on the outer label of packages of products that contain two or more separately packaged foods that are intended to be eaten individually (e.g., variety packs of cereals or snack foods) or of packages that are used interchangeably for the same type of food (e.g., round ice cream containers) may use an aggregate display.

(ii) Aggregate displays shall comply with the format requirements of paragraph (d) of this section to the maximum extent possible, except that the identity of each food shall be specified immediately under 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. The following sample label illustrates an aggregate display.



Nutrition Facts

	Wheat Squares Sweetened		Corn Flakes Not Sweetened		Mixed Grain Flakes Sweetened	
Serving Size 1 Box	(35g)		(19g)		(27g)	
Servings Per Container	1		1		1	
Amount Per Serving						
Calories	130		70		100	
Calories from Fat	0		0		0	
		% Daily Value*		**% Daily Value***		**% Daily Value***
Total Fat	0g	**0%**	0g	**0%**	0g	**0%**
Saturated Fat	0g	**0%**	0g	**0%**	0g	**0%**
Trans Fat	0g		0g		0g	
Cholesterol	0mg	**0%**	0mg	**0%**	0mg	**0%**
Sodium	0mg	**0%**	200mg	**8%**	120mg	**5%**
Potassium	125mg	**4%**	25mg	**1%**	30mg	**1%**
Total Carbohydrate	29g	**10%**	17g	**6%**	24g	**8%**
Dietary Fiber	3g	**12%**	1g	**4%**	1g	**4%**
Sugars	8g		6g		13g	
Protein	4g		1g		1g	
Vitamin A	0%		10%		10%	
Vitamin C	0%		15%		90%	
Calcium	0%		0%		0%	
Iron	10%		6%		20%	
Thiamin	30%		15%		20%	
Riboflavin	30%		15%		20%	
Niacin	30%		15%		20%	
Vitamin B_6	30%		15%		20%	

* 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
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

View or download PDF

(14) In accordance with 101.15(c)(2), when nutrition labeling must appear in a second language, the nutrition information may be presented in a separate nutrition label for

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 food (e.g., both "as purchased" and "as prepared") or for common combinations of food as provided for in paragraph (h)(4) of this section, for different units (e.g., slices of bread or 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 shown in paragraph (e)(5) 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 food (e.g., "Mix" and "Baked"), the combinations of food, 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 101.12(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 food, for combinations of food, 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 101.12(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 101.12(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:

Nutrition Facts

Serving Size 1/12 package (44g, about 1/4 cup dry mix)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	140
	% Daily Value**	
Total Fat 5g*	8%	24%
Saturated Fat 2g	10%	13%
Trans Fat 1g		
Cholesterol 0mg	0%	23%
Sodium 300mg	13%	13%
Total Carbohydrate 34g	11%	11%
Dietary Fiber 0g	0%	0%
Sugars 18g		
Protein 2g		
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

View or download PDF

(f) The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron; except that for foods intended for children less than 2 years of age to which 101.9(j)(5)(i) applies, nutrition information may be presented in the simplified format when a food product contains insignificant amounts of six or more of the following: Calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron.

(1) An "insignificant amount" shall be defined as that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount that allows a declaration of "less than 1 gram."

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

(i) Total calories, total fat, total carbohydrate, protein, and sodium;

(ii) Calories from fat and any other nutrients identified in paragraph (f) of this section that are present in the food in more than insignificant amounts; and

(iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are required to be added as a nutrient supplement to foods for which a standard of identity exists.

(iv) Any vitamins or minerals listed in paragraph (c)(8)(iv) of this section voluntarily added to the food as nutrient supplements.

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

(4) If any nutrients are declared as provided in paragraphs (f)(2)(iii), (f)(2)(iv), or (f)(3) of this section as part of the simplified format or if any nutrition claims are made on the label or in labeling, the statement "Not a significant source of ___" (with the blank filled in with the name(s) of any nutrient(s) identified in 101.9(f) and calories from fat that are present in insignificant amounts) shall be included at the bottom of the nutrition label.

(5) Except as provided for in paragraphs (j)(5) and (j)(13) of this section, nutrient information declared in the simplified format shall be presented in the same manner as

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) Compliance with this section shall be determined as follows:

(1) A collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, or in the absence of any common container code or marking, a day's production, constitutes a "lot."

(2) The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified in paragraph (c) of this section, composites shall be analyzed by appropriate methods as given in the "Official Methods of Analysis of the AOAC International," 15th Ed. (1990), which is incorporated by reference in accordance with 5 U.S.C. 552(a) or 1 CFR part 51 or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures. The availability of this incorporation by reference is given in paragraph (c)(7) of this section.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) *Class I.* Added nutrients in fortified or fabricated foods; and

(ii) *Class II.* Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to class II requirements unless the same nutrient is also added.

(4) A food with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act) unless it meets the following requirements:

(i) *Class I vitamin, mineral, protein, dietary fiber, or potassium.* The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) *Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium.* The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label. *Provided,* That no regulatory action will be based on a determination of a nutrient value that falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(5) A food with a label declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. *Provided,* That no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(6) Reasonable excesses of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium over labeled amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) Compliance with the provisions set forth in paragraphs (g)(1) through (g)(6) of this section may be provided by use of an FDA approved data base that has been computed following FDA guideline procedures and where food samples have been handled in accordance with current good manufacturing practice to prevent nutrition loss. FDA approval of a

with current good manufacturing practice to prevent nutrition loss. FDA approval of a data base shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the data base in writing. The approval will be granted where a clear need is presented (e.g., raw produce and seafood). Approvals will be in effect for a limited time, e.g., 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices. Approval requests shall be submitted in accordance with the provisions of 10.30 of this chapter. Guidance in the use of data bases may be found in the "FDA Nutrition Labeling Manual--A Guide for Developing and Using Data Bases," available from the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

(9) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section (e.g., to develop adequate nutrient profiles to comply with the requirements of paragraph (c) of this section), FDA may permit alternative means of compliance or additional exemptions to deal with the situation. Firms in need of such special allowances shall make their request in writing to the Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

(h) Products with separately packaged ingredients or foods, with assortments of food, or to which other ingredients are added by the user may be labeled as follows:

(1) If a product consists of two or more separately packaged ingredients enclosed in an outer container or of assortments of the same type of food (e.g., assorted nuts or candy mixtures) in the same retail package, nutrition labeling shall be located on the outer container or retail package (as the case may be) to provide information for the consumer at the point of purchase. However, when two or more food products are simply combined together in such a manner that no outer container is used, or no outer label is available, each product shall have its own nutrition information, e.g., two boxes taped together or two cans combined in a clear plastic overwrap. When separately packaged ingredients or assortments of the same type of food are intended to be eaten at the same time, the nutrition information may be specified per serving for each component or as a composite value.

(2) If a product consists of two or more separately packaged foods that are intended to be eaten individually and that are enclosed in an outer container (e.g., variety packs of cereals or snack foods), the nutrition information shall:

(i) Be specified per serving for each food in a location that is clearly visible to the consumer at the point of purchase; and

(ii) Be presented in separate nutrition labels or in one aggregate nutrition label with separate columns for the quantitative amount by weight and the percent Daily Value for each food.

(3) If a package contains a variety of foods, or an assortment of foods, and is in a form intended to be used as a gift, the nutrition labeling shall be in the form required by paragraphs (a) through (f) of this section, but it may be modified as follows:

(i) Nutrition information may be presented on the label of the outer package or in labeling within or attached to the outer package.

(ii) In the absence of a reference amount customarily consumed in 101.12(b) that is appropriate for the variety or assortment of foods in a gift package, 1 ounce for solid foods, 2 fluid ounces for nonbeverage liquids (e.g., syrups), and 8 fluid ounces for beverages may be used as the standard serving size for purposes of nutrition labeling of foods subject to this paragraph. However, the reference amounts customarily consumed in 101.12(b) shall be used for purposes of evaluating whether individual foods in a gift package qualify for nutrient content claims or health claims.

(iii) The number of servings per container may be stated as "varied."

(iv) Nutrition information may be provided per serving for individual foods in the package, or, alternatively, as a composite per serving for reasonable categories of foods in the package having similar dietary uses and similar significant nutritional characteristics. Reasonable categories of foods may be used only if accepted by FDA. In

characteristics. Reasonable categories of foods may be used only if accepted by FDA. In determining whether a proposed category is reasonable, FDA will consider whether the values of the characterizing nutrients in the foods proposed to be in the category meet

bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section;
(iii) Sold only in such facilities, *Provided,* That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section;
(iv) Used only in such facilities and not served to the consumer in the package in which they are received (e.g., foods that are not packaged in individual serving containers); or
(v) Sold by a distributor who principally sells food to such facilities: *Provided,* That:
(A) This exemption shall not be available for those foods that are manufactured, processed, or repackaged by that distributor for sale to any persons other than restaurants or other establishments that serve food for immediate human consumption, and
(B) The manufacturer of such products is responsible for providing the nutrition information on the products if there is a reasonable possibility that the product will be purchased directly by consumers.
(3) Food products that are:
(i) Of the type of food described in paragraphs (j)(2)(i) and (j)(2)(ii) of this section,
(ii) Ready for human consumption,
(iii) Offered for sale to consumers but not for immediate human consumption,
(iv) Processed and prepared primarily in a retail establishment, and
(v) Not offered for sale outside of that establishment (e.g., ready-to-eat foods that are processed and prepared on-site and sold by independent delicatessens, bakeries, or retail confectionery stores where there are no facilities for immediate human consumption; by in-store delicatessen, bakery, or candy departments; or at self-service food bars such as salad bars), *Provided,* That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section.
(4) Foods that contain insignificant amounts of all of the nutrients and food components required to be included in the declaration of nutrition information under paragraph (c) of this section, *Provided,* That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section. An insignificant amount of a nutrient or food component shall be that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount that allows a declaration of "less than 1 gram." Examples of foods that are exempt under this paragraph include coffee beans (whole or ground), tea leaves, plain unsweetened instant coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors.
(5)(i) Foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age shall bear nutrition labeling, except as provided in paragraph (j)(5)(ii) and except that such labeling shall not include calories from fat (paragraph (c)(1)(ii) of this section), calories from saturated fat ((c)(1)(iii)), saturated fat ((c)(2)(i)), polyunsaturated fat ((c)(2)(ii)), monounsaturated fat ((c)(2)(iii)), and cholesterol ((c)(3)).
(ii) Foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years of age shall bear nutrition labeling, except that:
(A) Such labeling shall not include declarations of percent of Daily Value for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber;
(B) Nutrient names and quantitative amounts by weight shall be presented in two separate columns.
(C) The heading "Percent Daily Value" required in paragraph (d)(6) of this section shall be placed immediately below the quantitative information by weight for protein;
(D) Percent of Daily Value for protein, vitamins, and minerals shall be listed immediately below the heading "Percent Daily Value"; and

(E) Such labeling shall not include the footnote specified in paragraph (d)(9) of this section.
(6) Dietary supplements, except that such foods shall be labeled in compliance with 101.36.
(7) Infant formula subject to section 412 of the act, as amended, except that such foods shall be labeled in compliance with part 107 of this chapter.
(8) Medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). A medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. A food is subject to this exemption only if:
(i) It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;
(ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;
(iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
(iv) It is intended to be used under medical supervision; and
(v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.
(9) Food products shipped in bulk form that are not for distribution to consumers in such form and that are for use solely in the manufacture of other foods or that are to be

(A) The manufacturer, packer, or distributor shall provide on the label of packages that qualify for and use this exemption an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., "For nutrition information, call 1-800-123-4567").
(B) When such products bear nutrition labeling, either voluntarily or because nutrition claims or other nutrition information is provided, all required information shall be in type size no smaller than 6 point or all uppercase type of 1/16 inches minimum height, except that individual serving-size packages of food served with meals in restaurants, institutions, and on board passenger carriers, and not intended for sale at retail, may comply with 101.2(c)(5).
(ii) 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) and (i) of this section by one or more of the following means:
(A) Presenting the required nutrition information in a tabular or, as provided below, 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 label will not accommodate a tabular display.
(*1*) The following sample label illustrates the tabular display.

View or download PDF

(*2*) The following sample label illustrates the linear display. When nutrition information is given in a linear fashion, bolding is required only on the title "Nutrition Facts" and is allowed voluntarily for the nutrient names for "Calories," "Total fat," "Cholesterol," "Sodium," "Total carbohydrate," and "Protein."

View or download PDF

(B) 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
(C) 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

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."
(D) Presenting the required nutrition information on any label panel.
(14) Shell eggs packaged in a carton that has a top lid designed to conform to the shape of the eggs are exempt from outer carton label requirements where the required nutrition information is clearly presented immediately beneath the carton lid or in an insert that can be clearly seen when the carton is opened.
(15) The unit containers in a multiunit retail food package where:
(i) The multiunit retail food package labeling contains all nutrition information in accordance with the requirements of this section;
(ii) The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and
(iii) Each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than 1/16-inch in height, except that this statement shall not be required when the inner unit containers bear no labeling at all. The word "individual" may be used in lieu of or immediately preceding the word "Retail" in the statement.
(16) Food products sold from bulk containers: *Provided,* That nutrition information required by this section be displayed to consumers either on the labeling of the bulk container plainly in view or in accordance with the provisions of paragraph (a)(2) of this section.
(17) Foods in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required information may use any alternate panel that can be readily seen by consumers for the nutrition label. The space needed for vignettes, designs, and other nonmandatory label information on the principal display panel may be considered in determining the sufficiency of available space on the principal display panel for the placement of the nutrition label. Nonmandatory label information on the information panel shall not be considered in determining the sufficiency of available space for the placement of the nutrition label.
(18) Food products that are low-volume (that is, they meet the requirements for units sold in paragraphs (j)(18)(i) or (j)(18)(ii) of this section); that, except as provided in paragraph (j)(18)(iv) of this section, are the subject of a claim for an exemption that provides the information required under paragraph (j)(18)(iv) of this section, that is filed before the beginning of the time period for which the exemption is claimed, and that is filed by a person, whether it is the manufacturer, packer, or distributor, that qualifies to claim the exemption under the requirements for average full-time equivalent employees in paragraphs (j)(18)(i) or (j)(18)(ii) of this section; and whose labels, labeling, and advertising do not provide nutrition information or make a nutrient content or health claim.
(i) For food products first introduced into interstate commerce before May 8, 1994, the product shall be exempt for the period:
(A) Between May 8, 1995, and May 7, 1996, if, for the period between May 8, 1994, and May 7, 1995, the person claiming the exemption employed fewer than an average of 300 full-time equivalent employees and fewer than 400,000 units of that product were sold in the United States; and
(B) Between May 8, 1996, and May 7, 1997, if for the period between May 8, 1995, and May 7, 1996, the person claiming the exemption employed fewer than an average of 200 full-time equivalent employees and fewer than 200,000 units of that product were sold in the United States.
(ii) For all other food products, the product shall be eligible for an exemption for any 12-month period if, for the preceding 12 months, the person claiming the exemption employed fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of that product were sold in the United States, or in the case of a food product that was not sold in the 12-month period preceding the period for which exemption is claimed, fewer than 100,000 units of such product are reasonably anticipated to be

is claimed, fewer than 100,000 units of such product are reasonably anticipated to be sold in the United States during the period for which exemption is claimed.
(iii) If a person claims an exemption under paragraphs (j)(18)(i) or (j)(18)(ii) of this section for a food product and then, during the period of such exemption, the number of full-time equivalent employees of such person exceeds the appropriate number, or the number of food products sold in the United States exceeds the appropriate number, or, if at the end of the period of such exemption, the food product no longer qualifies for an exemption under the provisions of paragraphs (j)(18)(i) or (j)(18)(ii) of this section, such person shall have 18 months from the date that the product was no longer qualified as a low-volume product of a small business to comply with this section.
(iv) A notice shall be filed with the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 and contain the following information, except that if the person is not an importer and has fewer than 10 full-time equivalent employees, that person does not have to file a notice for any food product with annual sales of fewer than 10,000 total units:
(A) Name and address of person requesting exemption. This should include a telephone number or FAX number that can be used to contact the person along with the name of a specific contact;
(B) Names of the food products (including the various brand names) for which exemption is claimed;
(C) Name and address of the manufacturer, distributor, or importer of the food product for which an exemption is claimed, if different than the person that is claiming the exemption;
(D) The number of full-time equivalent employees. Provide the average number of full-time equivalent individuals employed by the person and its affiliates for the 12 months preceding the period for which a small business exemption is claimed for a product. The average number of full-time equivalent employees is to be determined by dividing the total number of hours of salary or wages paid to employees of the person and its affiliates by the number of hours of work in a year, 2,080 hours (i.e., 40 hours*52 weeks);
(E) Approximate total number of units of the food product sold by the person in the United States in the 12-month period preceding that for which a small business exemption is claimed. Provide the approximate total number of units sold, or expected to be sold, in a 12-month period for each product for which an exemption is claimed. For products that have been in production for 1 year or more prior to the period for which exemption is claimed, the 12-month period is the period immediately preceding the period for which an exemption is claimed. For other products, the 12-month period is the period for which an exemption is claimed; and
(F) The notice shall be signed by a responsible individual for the person who can certify the accuracy of the information presented in the notice. The individual shall certify that the information contained in the notice is a complete and accurate statement of the average number of full-time equivalent employees of this person and its affiliates and of the number of units of the product for which an exemption is claimed sold by the person. The individual shall also state that should the average number of full-time equivalent employees or the number of units of food products sold in the United States by the person exceed the applicable numbers for the time period for which exemption is claimed, the person will notify FDA of that fact and the date on which the number of employees or the number of products sold exceeded the standard.
(v) FDA may by regulation lower the employee or units of food products requirements of paragraph (j)(18)(ii) of this section for any food product first introduced into interstate commerce after May 8, 2002, if the agency determines that the cost of compliance with such lower requirement will not place an undue burden on persons subject to it.
(vi) For the purposes of this paragraph, the following definitions apply:

(A) *Unit* means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers.
(B) *Food product* means food in any sized package which is manufactured by a single manufacturer or which bears the same brand name, which bears the same statement of identity, and which has similar preparation methods.
(C) *Person* means all domestic and foreign affiliates, as defined in 13 CFR 121.401, of the corporation, in the case of a corporation, and all affiliates, as defined in 13 CFR 121.401, of a firm or other entity, when referring to a firm or other entity that is not a corporation.
(D) *Full-time equivalent employee* means all individuals employed by the person claiming the exemption. This number shall be determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in a year, 2,080 hours (i.e., 40 hours*52 weeks).
(k) A food labeled under the provisions of this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act if its label or labeling represents, suggests, or implies:
(1) That the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom. Information about the relationship of a dietary property to a disease or health-related condition may only be provided in conformance with the requirements of 101.14 and part 101, subpart E.
(2) That the lack of optimum nutritive quality of a food, by reason of the soil on which that food was grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.
(3) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.
(4) That a natural vitamin in a food is superior to an added or synthetic vitamin.
[58 FR 2175, Jan. 6, 1993, as amended at 58 FR 2227, 2533, Jan. 6, 1993; 58 FR 17104, Apr. 1, 1993; 58 FR 17328-17331, Apr. 2, 1993; 58 FR 44048, 44076, Aug. 18, 1993; 58 FR 59363, Nov. 9, 1993; 58 FR 60109, Nov. 15, 1993; 59 FR 371, Jan. 4, 1994; 59 FR 62317, Dec. 5, 1994; 60 FR 17205, Apr. 5, 1995; 60 FR 30788, June 12, 1995; 60 FR 67174, Dec. 28, 1995; 61 FR 8779, Mar. 5, 1996; 61 FR 14479, Apr. 2, 1996; 61 FR 40978, Aug. 7, 1996; 62 FR 15342, Mar. 31, 1997; 62 FR 49848, Sept. 23, 1997; 63 FR 14035, Mar. 24, 1998; 64 FR 12889, Mar. 16, 1999; 65 FR 56479, Sept. 19, 2000; 66 FR 56035, Nov. 6, 2001; 70 FR 41502, July 11, 2005]

Database Updated April 1, 2006