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(iii) Preferred mailing address (if different from the vending machine operator address), for purposes of receiving correspondence; and

(iv) Certification that the information submitted is true and accurate, that the person or firm submitting it is authorized to do so, and that each registered vending machine will be subject to the requirements of this section.

(v) Information should be submitted by email by typing complete information into the portable document format (PDF) form, saving it on the registrant's computer, and sending it by email to *menulawregistration@fda.hhs.gov*. If email is not available, the registrant can either fill in the PDF form and print it out (or print out the blank PDF and fill in the information by hand or typewriter), and either fax the completed form to 301–436–2804 or mail it to FDA, CFSAN Menu and Vending Machine Labeling Registration, White Oak Building 22, rm. 0209, 10903 New Hampshire Ave., Silver Spring, MD 20993.

(vi) Authorized officials of a vending machine operator who elect to be subject to the Federal requirements can register by visiting *http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm217762.htm*. FDA has created a form that contains fields requesting the information in paragraph (d) of this section and made the form available at this Web site. Registrants must use this form to ensure that complete information is submitted.

(vii) To keep the establishment's registration active, the authorized official of the vending machine operator must register every other year within 60 days prior to the expiration of the vending machine operator's current registration with FDA. Registration will automatically expire if not renewed.

(e) *Vending machine operator contact information*. (1) A vending machine operator that is subject to section 403(q)(5)(H)(viii) of the Federal Food, Drug, and Cosmetic Act or a vending machine operator that voluntarily registers to be subject to the requirements under paragraph (d) of this section must provide its contact information for vending machines selling covered vending machine food. The contact information must list the vending machine operator's name, telephone number, and mailing address or email address.

(2) The contact information must be readable and may be placed on the face of the vending machine, or otherwise must be placed with the calorie declarations as described in paragraph (c)(2)(ii) of this section (*i.e.*, on the sign in, on, or adjacent to the vending machine).

(f) *Signatures*. Signatures obtained under paragraph (d) of this section that meet the definition of electronic signatures in § 11.3(b)(7) of this chapter are exempt from the requirements of part 11 of this chapter.

[79 FR 71291, Dec. 1, 2014, as amended at 84 FR 57610, Oct. 28, 2019]

§ 101.9 Nutrition labeling of food.

(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 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 at least 200 percent and up to and including 300 percent of the applicable reference amount, the serving size shall be the amount that approximates the reference amount. In addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving size, the manufacturer shall provide a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per individual unit. The first column would be based on the serving size for the product and the second column would be based on the individual unit. The exemptions in paragraphs (b)(12)(i)(A), (B), and (C) of this section apply to this provision.

(E) 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.

(F) 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.

(G) 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).

(H) 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 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 ½ 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)(F) 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 ⅔ cup)'' and ''1 oz dry cheese mix (28 g/about 2 tbsp);'' declared as a composite value: ''4 oz (112 g/about ⅔ 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 that contains less than 200 percent of the applicable reference amount must be considered to be a single-serving container, and the entire content of the product must be labeled as one serving. In addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving, for a product that is packaged and sold individually that contains more than 150 percent and less than 200 percent of the applicable reference amount, the Nutrition Facts label may voluntarily provide, to the left of the column that provides nutrition information per container (*i.e.*, per serving), an additional column that lists the quantitative amounts and percent Daily Values per common household measure that most closely approximates the reference amount.

(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., ½ 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–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., 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, manufacturers may declare ''varied'' for the number of servings per container provided the nutrition information is based on the reference amount expressed in the appropriate household measure based on the hierarchy described in paragraph (b)(5) of this section. Random weight products are foods such as cheeses that are sold as random weights that vary in size, such that the net contents for different containers would vary. The manufacturer may provide the typical number of servings in parentheses 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 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.

(12)(i) Products that are packaged and sold individually and that contain at least 200 percent and up to and including 300 percent of the applicable reference amount must provide an additional column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values for the entire package, as well as a column listing the quantitative amounts and percent Daily Values for a serving that is less than the entire package (*i.e.*, the serving size derived from the reference amount). The first column would be based on the serving size for the product and the second column would be based on the entire contents of the package.

(A) This provision does not apply to products that meet the requirements to use the tabular format in paragraph (j)(13)(ii)(A)(*1*) of this section or to products that meet the requirements to use the linear format in paragraph (j)(13)(ii)(A)(*2*) of this section.

(B) This provision does not apply to raw fruits, vegetables, and seafood for which voluntary nutrition labeling is provided in the product labeling or advertising or when claims are made about the product.

(C) This provision does not apply to products that require further preparation and provide an additional column of nutrition information under paragraph (e) of this section, to products that are commonly consumed in combination with another food and provide an additional column of nutrition information under paragraph (e) of this section, to products that provide an additional column of nutrition information for two or more groups for which RDIs are established (*e.g.*, both infants and children less than 4 years of age), to popcorn products that provide an additional column of nutrition information per 1 cup popped popcorn, or to varied-weight products covered under paragraph (b)(8)(iii) of this section.

(ii) When a nutrient content claim or health claim is made on the label of a product that uses a dual column as required in paragraph (b)(2)(i)(D) or (b)(12)(i) of this section, the claim must be followed by a statement that sets forth the basis on which the claim is made, except that the statement is not required for products when the nutrient that is the subject of the claim meets the criteria for the claim based

on the reference amount for the product and the entire container or the unit amount. When a nutrient content claim is made, the statement must express that the claim refers to the amount of the nutrient per serving (*e.g.*, ''good source of calcium per serving'' or ''per X [insert unit]__serving'') or per reference amount (*e.g.*, ''good source of calcium per [insert reference amount (*e.g.*, per 8 ounces)]), as required based on §101.12(g). When a health claim is made, the statement shall be ''A serving of __ounces of this product conforms to such a diet.''

(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 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, USDA Handbook No. 74 (slightly revised, 1973),

(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;

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate (less the amount of non-digestible carbohydrates and sugar alcohols), and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised, 1973) pp. 9–11. A general factor of 2 calories per gram for soluble non-digestible carbohydrates shall be used. The general factors for caloric value of sugar alcohols provided in paragraph (c)(1)(i)(F) of this section shall be used;

(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;

(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; or

(F) Using the following general factors for caloric value of sugar alcohols: Isomalt—2.0 calories per gram, lactitol—2.0 calories per gram, xylitol—2.4 calories per gram, maltitol—2.1 calories per gram, sorbitol—2.6 calories per gram, hydrogenated starch hydrolysates—3.0 calories per gram, mannitol—1.6 calories per gram, and erythritol—0 calories per gram.

(ii) ''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 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories 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 where fatty acids are aliphatic carboxylic acids consisting of a chain of alkyl groups and characterized by a terminal carboxyl group. Amounts shall be expressed to the nearest 0.5 (½) 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 (½) 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 (½)-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 (½) 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 (½) 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 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) ''Fluoride'' (VOLUNTARY): A statement of the number of milligrams of fluoride in a specified serving of food may be declared voluntarily, except that when a claim is made about fluoride content, label declaration shall be required. Fluoride content shall be expressed as zero when the serving contains less than 0.1 milligrams of fluoride, to the nearest 0.1-milligram increment when the serving contains less than or equal to 0.8 milligrams of fluoride, and the nearest 0.2 milligram-increment when a serving contains more than 0.8 milligrams of fluoride. Bottled water that bears a statement about added fluoride, as permitted by §101.13(q)(8), must bear nutrition labeling that complies with requirements for the simplified format in paragraph (f) of this section.

(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. Dietary fiber is defined as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health. 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. The following isolated or synthetic nondigestible carbohydrate(s) have been determined by FDA to have physiological effects that are beneficial to human health and, therefore, shall be included in the calculation of the amount of dietary fiber: [beta]-glucan soluble fiber (as described in §101.81(c)(2)(ii)(A)), psyllium husk (as described in §101.81(c)(2)(ii)(B)(*1*)), cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose. The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of dietary fiber in the label and labeling of food when a mixture of dietary fiber, and added nondigestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food.

(A) ''Soluble fiber'' (VOLUNTARY): A statement of the number of grams of soluble dietary fiber in a serving may

be declared voluntarily except that when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber must meet the definition of dietary fiber in this paragraph (c)(6)(i). The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of soluble fiber in the label and labeling of food when a mixture of soluble fiber and added nondigestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food. 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 must meet the definition of dietary fiber in this paragraph (c)(6)(i). The manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of insoluble fiber in the label and labeling of food when a mixture of insoluble and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food. 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) ''Total Sugars'': A statement of the number of grams of sugars in a serving, except that the 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 of the total sugars content is not required and, as a result, not declared, the statement ''Not a significant source of total sugars'' shall be placed at the bottom of the table of nutrient values in the same type size. Total sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Total sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) ''Added Sugars'': A statement of the number of grams of added sugars in a serving, except that label declaration of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content. Except as provided for in paragraph (f) of this section, if a statement of the added sugars content is not required and, as a result, not declared, the statement ''Not a significant source of added sugars'' shall be placed at the bottom of the table of nutrient values in the same type size. Added sugars are either added during the processing of foods, or are packaged as such, and include sugars (free, mono and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type, except that fruit or vegetable juice concentrated from 100 percent juices sold to consumers, fruit or vegetable juice concentrates used towards the total juice percentage label declaration under § 101.30 or for Brix standardization under § 102.33(g)(2) of this chapter, fruit juice concentrates which are used to formulate the fruit component of jellies, jams, or preserves in accordance with the standard of identities set forth in §§ 150.140 and 150.160 of this chapter, or the fruit component of fruit spreads shall not be labeled as added sugars. Added sugars content

shall be indented under Total Sugars and shall be prefaced with the word ''Includes'' followed by the amount (in grams) ''Added Sugars'' (''Includes 'X' g Added Sugars''). It shall be 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 a mixture of naturally occurring and added sugars is present in the food, and for specific foods containing added sugars, alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation and/or non-enzymatic browning, the manufacturer must make and keep records in accordance with paragraphs (g)(10) and (11) of this section to verify the declared amount of added sugars in the label and labeling of food.

(iv) ''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 total sugars, or added 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 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 a 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 specifically for infants through 12 months, 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 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,'' except when official AOAC procedures described in this paragraph (c)(7) require a specific factor other than 6.25, that specific factor shall be used.

(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 specifically for infants through 12 months or children 1 through 3 years of age. When such a declaration is provided, it should 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 specifically for infants through 12 months 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 ''Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' except that when official AOAC procedures described in paragraph (c)(7) of this section require a specific factor other than 6.25, that specific factor shall be used. For foods represented or purported to be specifically for infants through 12 months, 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 DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, a value of 11 grams of protein shall be the RDI for infants through 12 months, a value of 13 grams shall be the DRV for children 1 through 3 years of age, and a value of 71 grams of protein shall be the RDI for pregnant women and lactating women.

(8) ''Vitamins and minerals'': The requirements related to including a statement of the amount per serving of vitamins and minerals are described in this paragraph (c)(8).

(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 specifically for infants through 12 months, children 1 through 3 years, pregnant women, and lactating women shall use the RDIs that are specified for the intended group. For foods represented or purported to be specifically for both infants through 12 months of age and children 1 through 3 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 through 12 months of age and children 1 through 3 years of age. 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. The percent Daily Value based on the RDI values for pregnant women and lactating women shall be declared on food represented or purported to be specifically for pregnant women and lactating women. 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 quantitative amount by weight and percent of the RDI shall include vitamin D, calcium, iron, and potassium in that order, for infants through 12 months, children 1 through 3 years of age, pregnant women, lactating women, and adults and children 4 or more years of age, except quantitative weights for these vitamins and minerals are not required for labels described in paragraph (j)(13) of this section. The declaration of folic acid shall be included as a quantitative amount by weight when added as a nutrient supplement or a claim is made about the nutrient. The declaration of vitamins and minerals in a food, as a quantitative amount by weight and percent of the RDI, may include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section. The declaration of vitamins and minerals shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section as a statement

of the amount per serving of the vitamins and minerals as described in this paragraph (c)(8)(ii), calculated as a percent of the RDI and expressed as a percent of the Daily Value, when they are added as a nutrient supplement, or when a claim is made about them, unless otherwise stated as quantitative amount by weight and percent of the Daily Value. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or the 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. Quantitative amounts and percentages 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 D, calcium, iron, or potassium 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. The quantitative amounts of vitamins and minerals, excluding sodium, shall be the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in paragraph (c)(8)(iv) of this section, except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (*e.g.*, the RDI for zinc is given in whole milligrams, but the quantitative amount may be declared in tenths of a milligram).

(iv) The following RDIs, nomenclature, and units of measure are established for the following vitamins and minerals which are essential in human nutrition:

		RDI			
Nutrient	Unit of measure	Adults and children ≥ 4 years	Infants [1] through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Vitamin D	Micrograms (mcg) [2]	20	10	15	15
Calcium	Milligrams (mg)	1,300	260	700	1,300
Iron	Milligrams (mg)	18	11	7	27
Potassium	Milligrams (mg)	4,700	700	3,000	5,100
Vitamin A	Micrograms RAE [3] (mcg)	900	500	300	1,300
Vitamin C	Milligrams (mg)	90	50	15	120
Vitamin E	Milligrams (mg) [4]	15	5	6	19
Vitamin K	Micrograms (mcg)	120	2.5	30	90
Thiamin	Milligrams (mg)	1.2	0.3	0.5	1.4
Riboflavin	Milligrams (mg)	1.3	0.4	0.5	1.6
Niacin	Milligrams NE [5] (mg)	16	4	6	18
Vitamin B_6	Milligrams (mg)	1.7	0.3	0.5	2.0
Folate [6]	Micrograms DFE [7] (mcg)	400	80	150	600

Nutrient	Unit of measure	RDI			
		Adults and children ≥ 4 years	Infants [1] through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Vitamin B_{12}	Micrograms (mcg)	2.4	0.5	0.9	2.8
Biotin	Micrograms (mcg)	30	6	8	35
Pantothenic acid	Milligrams (mg)	5	1.8	2	7
Phosphorus	Milligrams (mg)	1,250	275	460	1,250
Iodine	Micrograms (mcg)	150	130	90	290
Magnesium	Milligrams (mg)	420	75	80	400
Zinc	Milligrams (mg)	11	3	3	13
Selenium	Micrograms (mcg)	55	20	20	70
Copper	Milligrams (mg)	0.9	0.2	0.3	1.3
Manganese	Milligrams (mg)	2.3	0.6	1.2	2.6
Chromium	Micrograms (mcg)	35	5.5	11	45
Molybdenum	Micrograms (mcg)	45	3	17	50
Chloride	Milligrams (mg)	2,300	570	1,500	2,300
Choline	Milligrams (mg)	550	150	200	550
Protein	Grams (g)	N/A	11	N/A	[8] 71

[1] RDIs are based on dietary reference intake recommendations for infants through 12 months of age.
[2] The amount of vitamin D may, but is not required to, be expressed in international units (IU), in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IU must appear in parentheses after the declaration of the amount of vitamin D in mcg.
[3] RAE = Retinol activity equivalents; 1 microgram RAE = 1 microgram retinol, 2 microgram supplemental β-carotene, 12 micrograms dietary β-carotene, or 24 micrograms dietary α-carotene, or dietary 24 micrograms dietary β-cryptoxanthin.
[4] 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all rac*-α-tocopherol.
[5] NE = Niacin equivalents, 1 mg NE = 1 mg niacin = 60 milligrams tryptophan.
[6] ''Folate'' and ''Folic Acid'' must be used for purposes of declaration in the labeling of conventional foods and dietary supplements. The declaration for folate must be in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or a dietary supplement), and percent DV based on folate in mcg DFE. Folate may be expressed as a percent DV in conventional foods. When folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses, as mcg of folic acid.
[7] DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally occurring folate = 0.6 mcg folic acid.
[8] Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant women and lactating women.

(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 B_1
Riboflavin—Vitamin B_2

(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.

(vii) When the amount of folate is declared in the labeling of a conventional food or a dietary supplement, the nutrient name ''folate'' shall be listed for products containing folate (natural folate, and/or synthetic folate as a component of dietary supplement, such as calcium salt of L–5-MTHF), folic acid, or a mixture of folate and folic acid. The name of the synthetic form of the nutrient ''folic acid'', when added or a claim is made about the nutrient, shall be included in parentheses after this declaration with the amount of folic acid. The declaration must be folate in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or a dietary supplement) and the percent DV based on folate in mcg DFE, or for conventional food, may be expressed as folate and the percent DV based on folate in mcg DFE. When declared, folic acid must be in parentheses, mcg of folic acid as shown in paragraph (d)(12) of this section in the display that illustrates voluntary declaration of nutrition information.

(9) The following DRVs, nomenclature, and units of measure are established for the following food components:

Food component	Unit of measure	Adults and children ≥4 years	Infants through 12 months	Children 1 through 3 years	Pregnant women and lactating women
Fat	Grams (g)	[1] 78	30	[2] 39	[1] 78
Saturated fat	Grams (g)	[1] 20	N/A	[2] 10	[1] 20
Cholesterol	Milligrams (mg)	300	N/A	300	300
Total carbohydrate	Grams (g)	[1] 275	95	[2] 150	[1] 275
Sodium	Milligrams (mg)	2,300	N/A	1,500	2,300
Dietary Fiber	Grams (g)	[1] 28	N/A	[2] 14	[1] 28
Protein	Grams (g)	[1] 50	N/A	[2] 13	N/A
Added Sugars	Grams (g)	[1] 50	N/A	[2] 25	[1] 50

[1] Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant women and lactating women

[2] Based on the reference caloric intake of 1,000 calories for children 1 through 3 years of age.

(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 where the tabular display is permitted as provided for in paragraph (d)(11) of this section, 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 through 12 months of age and children 1 through 3 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 strongly recommends 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)(7) and (8) of this section shall be in type size no smaller than 8 point. Information required in paragraph (d)(5) of this section for the ''Calories'' declaration shall be highlighted in bold or extra bold and shall be in a type size no smaller than 16 point except the type size for this information required in the tabular displays as shown in paragraphs (d)(11), (e)(6)(ii), and (j)(13)(ii)(A)(*1*) of this section and the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section shall be in a type size no smaller than 10 point. The numeric amount for the information required in paragraph (d)(5) of this section shall also be highlighted in bold or extra bold type and shall be in a type size no smaller than 22 point, except the type size for this information required for the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(*1*) of this section, and for the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section no smaller than 14 point. The information required in paragraphs (d)(4), (6), and (9) of this section shall be in a type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall be in a type size no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(3)(ii), (d)(4), and (d)(6) of this section (*i.e.*, ''Nutrition Facts,'' ''Serving size,'' ''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'' and ''Protein''), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted in 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 ''Nutrition Facts'' from the servings per container statement required in paragraph (d)(3)(i) of this section and shall separate each nutrient and its corresponding percent Daily Value required in paragraphs (d)(7)(i) and (ii) of this section from the nutrient and percent Daily Value above and below it, as shown in paragraph (d)(12) of this section and in Appendix B to Part 101.

(2) The information shall be presented under the identifying heading of ''Nutrition Facts'' which shall be set in a type size no smaller than all other print size in the nutrition label except for the numerical information for ''Calories'' required in paragraph (d)(5) of this section, and except for labels presented according to the format provided for in paragraphs (d)(11), (d)(13)(ii), (e)(6)(ii), (j)(13)(ii)(A)(*1*), and (j)(13)(ii)(A)(*2*) 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 servings per container and serving size shall immediately follow the heading as shown in paragraph (d)(12) of this section. Such information shall include:

(i) ''____ 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. The information required in this paragraph shall be located immediately after the ''Nutrition Facts'' heading and shall be in a type size no smaller than 10 point, except the type size for this information shall be no smaller than 9 point in the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(*1*) of this section and the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section. For the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section, the actual number of servings may be listed after the servings per container declaration.

(ii) ''Serving size'': A statement of the serving size as specified in paragraph (b)(7) of this section which shall immediately follow the ''___servings per container'' declaration. The information required in this paragraph shall be highlighted in bold or extra bold and be in a type size no smaller than 10 point, except the type size shall be no smaller than 9 point for this information in the tabular displays as shown in paragraphs (d)(11) and (e)(6)(ii) of this section, the tabular display for small packages as shown in paragraph (j)(13)(ii)(A)(*1*) of this section, and the linear display for small packages as shown in paragraph (j)(13)(ii)(A)(*2*) of this section. The serving size amount must be right justified if adequate space is available. If the ''Serving size'' declaration does not fit in the allocated space a type size of no smaller than 8 point may be used on packages of any size.

(4) A subheading ''Amount per serving'' shall be separated from the serving size information by a bar as shown in paragraph (d)(12) of this section, except this information is not required for the dual column formats shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section.

(5) Information on calories shall immediately follow the subheading ''Amount per serving'' and shall be declared in one line. If ''Calories from saturated fat'' is declared, it shall be indented under ''Calories'' and shall be in a type size no smaller than 8 point.

(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)(ii)(A)(*2*) 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 for folic acid in conventional food and voluntarily declared vitamins and minerals expressed as a statement of the amount per serving calculated as a percent of the RDI and expressed as a percent Daily Value, 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, ''mg'' for milligrams, or ''mcg'' for micrograms 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., %).

(8) Nutrient information for vitamins and minerals (except sodium) shall be separated from information on other nutrients by a bar and may be arrayed vertically as shown in paragraph (d)(12) of this section (*e.g.*, Vitamin D 2 mcg 10%, Calcium 260 mg 20%, Iron 8 mg 45%, Potassium 235 mg 6%) or may be listed horizontally. When listed horizontally in two columns, vitamin D and calcium should be listed on the first line and iron and potassium should be listed on the second line, as shown in paragraph (d)(12) of this section in the side-by-side display. When more than four vitamins and minerals are declared voluntarily as shown in paragraph (d)(12) of this section in the label which illustrates the mandatory plus voluntary provisions of paragraph (d) of this section, 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 the list by a bar, except that the footnote may be omitted from foods that can use the terms ''calorie free,'' ''free of calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietary insignificant source of calories'' on the label or in the labeling of foods as defined in §101.60(b). The first sentence of the footnote: ''The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet'' may be used on foods that can use the terms ''calorie free,'' ''free of calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietary insignificant source of calories'' on the label or in the labeling of foods as defined in §101.60(b). The footnote shall state: ''*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.'' If the food product is represented or purported to be for children 1 through 3 years of age, the second sentence of the footnote shall substitute ''1,000 calories'' for ''2,000 calories.''

(10) Caloric conversion information on a per gram basis for fat, carbohydrate, and protein may be presented beneath the information required in

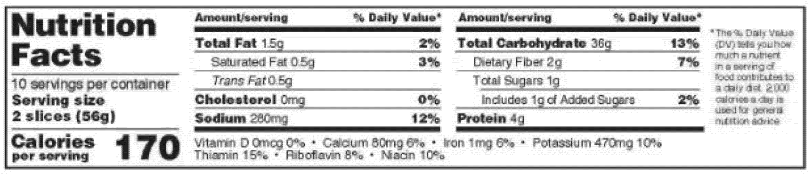
paragraph (d)(9) of this section, separated from that information by a hairline. This information may be presented horizontally as shown in paragraph (d)(12) of this section (i.e., ''Calories per gram: fat 9, carbohydrate 4, protein 4'') or vertically in columns.

(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 potassium 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 potassium, the nutrition label may be presented in a tabular display as shown in the following sample label.

Tabular Format



Nutrition Facts	Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
10 servings per container	**Total Fat** 1.5g	2%	**Total Carbohydrate** 36g	13%
Serving size	Saturated Fat 0.5g	3%	Dietary Fiber 2g	7%
2 slices (56g)	*Trans Fat* 0.5g		Total Sugars 1g	
Calories per serving 170	**Cholesterol** 0mg	0%	Includes 1g of Added Sugars	2%
	Sodium 280mg	12%	**Protein** 4g	

Vitamin D 0mcg 0% • Calcium 80mg 6% • Iron 1mg 6% • Potassium 470mg 10%
Thiamin 15% • Riboflavin 8% • Niacin 10%

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(12) The following sample labels illustrate the mandatory provisions and mandatory plus voluntary provisions of paragraph (d) of this section and the side-by-side display.

Standard Vertical

Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

Amount per serving

Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Standard Vertical
(w/ Voluntary)

Nutrition Facts

17 servings per container
Serving size **3/4 cup (28g)**

Amount per serving
Calories **140**

	% Daily Value*
Total Fat 1.5g	**2%**
Saturated Fat 0g	**0%**
Trans Fat 0g	
Polyunsaturated Fat 0.5g	
Monounsaturated Fat 0.5g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 22g	**8%**
Dietary Fiber 2g	**7%**
Soluble Fiber <1g	
Insoluble Fiber 1g	
Total Sugars 9g	
Includes 8g Added Sugars	**16%**
Protein 9g	**18%**
Vitamin D 2mcg (80 IU)	10%
Calcium 130mg	10%
Iron 4.5mg	25%
Potassium 115mg	2%
Vitamin A 90mcg	10%
Vitamin C 9mg	10%
Thiamin 0.3mg	25%
Riboflavin 0.3mg	25%
Niacin 4mg	25%
Vitamin B_6 0.4mg	25%
Folate 200mcg DFE (120mcg folic acid)	50%
Vitamin B_{12} 0.6mcg	25%
Phosphorus 100mg	8%
Magnesium 25mg	6%
Zinc 3mg	25%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

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

Standard Vertical
(Side-by-Side Display)

Nutrition Facts

8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving
Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	

Vit. D 2mcg 10% • Calcium 260mg 20%
Iron 8mg 45% • Potas. 235mg 6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(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 to the right of the ''Nutrition Facts'' heading, and both the quantitative amount by weight (*i.e.*, g/mg/mcg 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.

Aggregate Display

Nutrition Facts	Wheat Squares Sweetened		Corn Flakes Not Sweetened		Mixed Grain Flakes Sweetened	
1 serving per container						
Serving size 1 box	(35g)		(19g)		(27g)	
Amount per serving						
Calories	**130**		**70**		**100**	
		% 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	**9%**	120mg	**5%**
Total Carbohydrate	29g	**11%**	17g	**6%**	24g	**9%**
Dietary Fiber	3g	**11%**	1g	**4%**	1g	**4%**
Total Sugars	8g		6g		13g	
Includes Added Sugars	8g	**16%**	5g	**10%**	13g	**26%**
Protein	4g		1g		1g	
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice						
Vitamin D	2mcg	10%	2mcg	10%	0mcg	0%
Calcium	0mg	0%	0mg	0%	0mg	0%
Iron	2mg	10%	1mg	6%	4mg	20%
Potassium	125mg	4%	25mg	1%	30mg	1%
Vitamin A		0%		10%		10%
Vitamin C		0%		15%		90%
Thiamin		35%		15%		25%
Riboflavin		30%		10%		25%
Niacin		30%		10%		20%
Vitamin B_6		30%		20%		20%

(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 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 RDIs are established (*e.g.*, both infants through 12 months of age and children 1 through 3 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 serving size information there shall be two or more column headings accurately describing the amount per serving size of the form of the same food (*e.g.*, ''Per ¼ cup mix'' and ''Per prepared portion''), the combinations of food, the units, or the RDI groups that are being declared as shown in paragraph (e)(5) of this section.

(2) The quantitative information by weight as required in paragraph (d)(7)(i) and the information required in paragraph (d)(7)(ii) of this section shall be presented for the form of the product as packaged and for any other form of the product (*e.g.*, ''as prepared'' or combined with another ingredient as shown in paragraph (e)(5) of this section).

(3) When the dual labeling is presented for two or more forms of the

same food, for combinations of food, for different units, or for two or more groups for which RDIs are established, the quantitative information by weight and the percent Daily Value shall be presented in two columns and the columns shall be separated by vertical lines as shown in paragraph (e)(5) of this section.

(4) Nutrient information for vitamins and minerals (except sodium) shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, potassium as shown in paragraph (e)(5) of this section.

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

Dual Columns, Two Forms of the Same Food

Nutrition Facts

12 servings per container

Serving size **1/4 cup dry mix (44g)**

	Per 1/4 cup dry mix		Per baked portion	
Calories	**170**		**300**	
		% DV*		% DV*
Total Fat	1.5g	**2%**	16g	**21%**
Saturated Fat	1g	**5%**	5g	**25%**
Trans Fat	0g		0g	
Cholesterol	0mg	**0%**	60mg	**20%**
Sodium	300mg	**13%**	375mg	**16%**
Total Carb.	36g	**13%**	36g	**13%**
Dietary Fiber	<1g	**2%**	<1g	**2%**
Total Sugars	18g		18g	
Incl. Added Sugars	18g	**36%**	18g	**36%**
Protein	2g		3g	
Vitamin D	0mcg	0%	0mcg	0%
Calcium	100mg	8%	100mg	8%
Iron	1mg	6%	1mg	6%
Potassium	40mg	0%	40mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(6) When dual labeling is presented for a food on a per serving basis and per container basis as required in paragraph (b)(12)(i) of this section or on a per serving basis and per unit basis as required in paragraph (b)(2)(i)(D) of

this section, the quantitative information by weight as required in paragraph (d)(7)(i) and the percent Daily Value as required in paragraph (d)(7)(ii) shall be presented in two columns, and the columns shall be separated by vertical lines as shown in the displays in paragraph (e)(6)(i) of this section.

(i) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, and potassium as shown in the following sample labels.

Dual Column Display, Per Serving and Per Container

Nutrition Facts

2 servings per container

Serving size **1 cup (255g)**

	Per serving		Per container	
Calories	**220**		**440**	
		% DV*		% DV*
Total Fat	5g	**6%**	10g	**13%**
Saturated Fat	2g	**10%**	4g	**20%**
Trans Fat	0g		0g	
Cholesterol	15mg	**5%**	30mg	**10%**
Sodium	240mg	**10%**	480mg	**21%**
Total Carb.	35g	**13%**	70g	**25%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Dual Columns, Per Serving and Per Unit

Nutrition Facts

12 servings per container
Serving size **1/2 muffin (144g)**

	Per 1/2 muffin		Per 1 muffin	
Calories	**380**		**760**	
		% DV*		% DV*
Total Fat	16g	**21%**	32g	**41%**
Saturated Fat	3g	**15%**	6g	**30%**
Trans Fat	0g		0g	
Cholesterol	50mg	**17%**	100mg	**33%**
Sodium	480mg	**21%**	960mg	**42%**
Total Carb.	56g	**20%**	112g	**41%**
Dietary Fiber	2g	**7%**	4g	**14%**
Total Sugars	32g		64g	
Incl. Added Sugars	30g	**60%**	60g	**120%**
Protein	3g		6g	
Vitamin D	0.1mcg	0%	0.2mcg	2%
Calcium	40mg	4%	80mg	6%
Iron	2mg	10%	4mg	20%
Potassium	190mg	4%	380mg	8%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(ii) The following sample label illustrates the provisions of paragraphs (b)(2)(i)(D) and (b)(12)(i) of this section for labels that use the tabular display.

Tabular Dual Column Display

Nutrition Facts

2 servings per container
Serving size
1 cup (255g)

Calories
220 per serving | **440** per container

	Per serving	% DV*	Per container	% DV*		Per serving	% DV*	Per container	% DV*
Total Fat	5g	**6%**	10g	**13%**	**Total Carb.**	35g	**13%**	70g	**25%**
Saturated Fat	2g	**10%**	4g	**20%**	Dietary Fiber	6g	**21%**	12g	**43%**
Trans Fat	0g		0g		Total Sugars	7g		14g	
Cholesterol	15mg	**5%**	30mg	**10%**	Incl. Added Sugars	4g	**8%**	8g	**16%**
Sodium	240mg	**10%**	480mg	**21%**	**Protein**	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%	Iron	1mg	6%	2mg	10%
Calcium	200mg	15%	400mg	30%	Potassium	470mg	10%	940mg	20%

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(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, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium; except that for foods intended for infants through 12 months of age and children 1 through 3 years of age to which paragraph (j)(5)(i) of this section 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, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium.

(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) 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 paragraph (f) of this section that are present in insignificant amounts) shall be included at the bottom of the nutrition label.

Simplified Display

(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 specified in paragraphs (d) or (e) of this section, except that the footnote required in paragraph (d)(9) of this section is not required, and an asterisk shall be placed at the bottom of the label followed by the statement ''% DV = % Daily Value'' when ''Daily Value'' is not spelled out in the heading, as shown in paragraph (f)(4).

(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,'' or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures.

(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. When a nutrient is naturally occurring (indigenous) in a food or an ingredient that is added to a food, the total amount of such nutrient in the final food product is subject to class II requirements, except that when an exogenous source of the nutrient is also added to the final food product, the total amount of the nutrient in the final food product (indigenous and exogenous) is subject to class I requirements.

(4) A food with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, polyunsaturated or monounsaturated fat 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) When a vitamin, mineral, protein, or dietary fiber meets the definition of a Class I nutrient, the nutrient content of the composite must be formulated to be at least equal to the value for that nutrient declared on the label.

(ii) When a vitamin, mineral, protein, total carbohydrate, polyunsaturated or monounsaturated fat, or dietary fiber meets the definition of a Class II nutrient, the nutrient content of the composite must be 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, total sugars, added sugars (when the only source of sugars in the food is added 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 vitamins, minerals, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugar alcohols, polyunsaturated or monounsaturated fat over labeled amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, total sugars, added 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) Alternatively, compliance with the provisions set forth in paragraphs (g)(1) through (6) of this section may be provided by use of an FDA approved database 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 database shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the database 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 databases may be found in the ''FDA Nutrition Labeling Manual—A Guide for Developing and Using Data Bases,'' available from the Office of Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740 or by going to *http://www.fda.gov*.

(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, 5001 Campus Dr., College Park, MD 20740.

(10) The manufacturer must make and keep written records (*e.g.*, analyses of databases, recipes, formulations, information from recipes or formulations, or batch records) to verify the declared amount of that nutrient on the Nutrition Facts label as follows:

(i) When a mixture of dietary fiber, and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food, a manufacturer must make and keep written records of the amount of non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(ii) When a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food, a manufacturer must make and keep written records necessary to verify the amount of the non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(iii) When a mixture of insoluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food, a manufacturer must make and keep written records necessary to verify the amount of the non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(iv) When a mixture of naturally occurring and added sugars is present in the food, a manufacturer must make and keep written records of the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient).

(v) When the amount of sugars added to food products is reduced through non-enzymatic browning and/or fermentation, manufacturers must:

(A) Make and keep records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after non-enzymatic browning and/or fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food that is subject to non-enzymatic browning and/or fermentation; or

(B) Make and keep records of the amount of added sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether

as part of a package containing one or more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label; or

(C) Submit a petition, under 21 CFR 10.30, to request an alternative means of compliance. The petition must provide scientific data or other information for why the amount of added sugars in a serving of the product is likely to have a significant reduction in added sugars compared to the amount added prior to non-enzymatic browning and/or fermentation. A significant reduction would be where reduction in added sugars after non-enzymatic browning and/or fermentation may be significant enough to impact the label declaration for added sugars by an amount that exceeds the reasonable deficiency acceptable within good manufacturing practice under paragraph (g)(6) of this section. In addition, the scientific data or other information must include the reason that the manufacturer is unable to determine a reasonable approximation of the amount of added sugars in a serving of their finished product and a description of the process that they used to come to that conclusion.

(vi) When a mixture of *all rac*-α-tocopherol and RRR-α-tocopherol is present in a food, manufacturers must make and keep written records of the amount of *all rac*-α-tocopherol added to the food and RRR-α-tocopherol in the finished food.

(vii) When a mixture of folate and folic acid is present in a food, manufacturers must make and keep written records of the amount of synthetic folate and/or folic acid added to the food and the amount of naturally-occurring folate in the finished food.

(11) Records necessary to verify certain nutrient declarations that are specified in paragraph (g)(10) of this section must be kept for a period of at least 2 years after introduction or delivery for introduction of the food into interstate commerce. Such records must be provided to FDA upon request, during an inspection, for official review and photocopying or other means of reproduction. Records required to verify information on the label may be kept either as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records which must be kept in accordance with part 11 of this chapter. These records must be accurate, indelible, and legible.

Failure to make and keep the records or provide the records to appropriate regulatory authorities, as required by this paragraph (g)(11), would result in the food being misbranded under section 403(a)(1) of the act.

(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, the following may be used as the standard serving size for purposes of nutrition labeling of foods subject to this paragraph: 1 ounce for solid foods; 2 fluid ounces for nonbeverage liquids (*e.g.*, syrups); 8 ounces for beverages that consist of milk and fruit juices, nectars and fruit drinks; and 12 fluid ounces for other beverages. 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 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 the compliance criteria set forth in paragraphs (g)(3) through (6) of this section. Proposals for such categories may be submitted in writing to the Office of Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740.

(v) If a food subject to paragraph (j)(13) of this section because of its small size is contained in a gift package, the food need not be included in the determination of nutrition information under paragraph (h) of this section if it is not specifically listed in a promotional catalogue as being present in the gift package, and:

(A) It is used in small quantities primarily to enhance the appearance of the gift package; or

(B) It is included in the gift package as a free gift or promotional item.

(4) If a food is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare nutrition information on the basis of the food as consumed in the format required in paragraph (e) of this section; *e.g.*, a dry ready-to-eat cereal may be described with the percent Daily Value and the quantitative amounts for the cereal as sold (*e.g.*, per ounce), and the percent Daily Value and the quantitative amounts for the cereal and milk as suggested in the label (*e.g.*, per ounce of cereal and ½cup of vitamin D fortified skim milk); and a cake mix may be labeled with the percent Daily Value and the quantitative amounts for the dry mix (per serving) and the percent Daily Value and the quantitative amounts for the serving of the final cake when prepared, as shown in paragraph (e)(5) of this section: Provided, that, the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(i) Except as provided in paragraphs (j)(13) and (j)(17) of this section, the location of nutrition information on a label shall be in compliance with § 101.2.

(j) The following foods are exempt from this section or are subject to special labeling requirements:

(1)(i) Food offered for sale by a person who makes direct sales to consumers (*e.g.*, a retailer) who has annual gross sales made or business done in sales to consumers that is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, *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, § 101.10, or § 101.11, as applicable.

(ii) For purposes of this paragraph, calculation of the amount of sales shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years, reasonable estimates must indicate that annual sales will not exceed the amounts specified. For foreign firms that ship foods into the United States, the business activities to be included shall be the total amount of food sales, as well as other sales to consumers, by the firm in the United States.

(2) Except as provided in § 101.11, food products that are:

(i) Served in restaurants, *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;

(ii) Served in other establishments in which food is served for immediate human consumption (*e.g.*, institutional food service establishments, such as schools, hospitals, and cafeterias; transportation carriers, such as trains and airplanes; bakeries, delicatessens, and retail confectionery stores where there are facilities for immediate consumption on the premises; food service vendors, such as lunch wagons, ice cream shops, mall cookie counters, vending machines, and sidewalk carts where foods are generally consumed immediately where purchased or while the consumer is walking away, including similar foods sold from convenience stores; and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices), *Provided*, That the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising, except as provided in § 101.8(c). Claims or other nutrition information, except as provided in § 101.8(c), 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) Except as provided in § 101.11, 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) Except as provided in § 101.11, 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, except as provided in §101.8(c), 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 through 12 months of age and children 1 through 3 years of age shall bear nutrition labeling. The nutrients declared for infants through 12 months of age and children 1 through 3 years of age shall include calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrates, dietary fiber, total sugars, added sugars, protein, and the following vitamins and minerals: Vitamin D, calcium, iron, and potassium.

(ii) Foods, other than infant formula, represented or purported to be specifically for infants through 12 months of age shall bear nutrition labeling, except that:

(A) Such labeling shall not declare a percent Daily Value for saturated fat, *trans* fat, cholesterol, sodium, dietary fiber, total sugars, or added sugars and shall not include a footnote.

(B) The following sample label illustrates the provisions of paragraph (j)(5)(ii) of this section.

Infants through 12 Months of Age

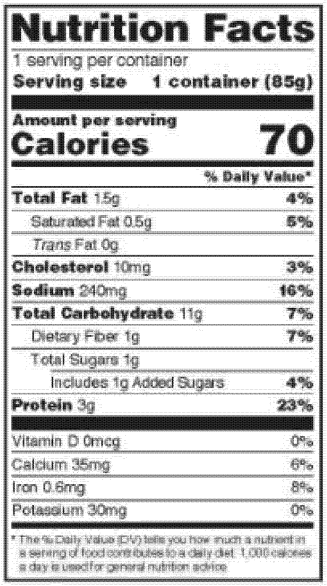
Nutrition Facts	
4 servings per container	
Serving size	**1 pack (70g)**
Amount per serving	
Calories	**25**
	% Daily Value
Total Fat 0g	**0%**
Saturated Fat 0g	
Trans Fat 0g	
Cholesterol 0mg	
Sodium 74mg	
Total Carbohydrate 5g	**5%**
Dietary Fiber 1g	
Total Sugars 3g	
Includes 0g Added Sugars	
Protein 0g	**0%**
Vitamin D 0mcg	0%
Calcium 5mg	2%
Iron 1mg	10%
Potassium 230mg	35%

(C)–(E) [Reserved]

(iii) Foods, other than infant formula, represented or purported to be specifically for children 1 through 3 years of age shall include a footnote that states: ''*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 1,000 calories a day is used for general nutrition advice.''

(A) The following sample label illustrates the provisions of paragraph (j)(5)(iii) of this section.

Children 1-3 Years



Nutrition Facts

1 serving per container

Serving size 1 container (85g)

Amount per serving

Calories 70

	% Daily Value*
Total Fat 1.5g	**4%**
Saturated Fat 0.5g	**5%**
Trans Fat 0g	
Cholesterol 10mg	**3%**
Sodium 240mg	**16%**
Total Carbohydrate 11g	**7%**
Dietary Fiber 1g	**7%**
Total Sugars 1g	
Includes 1g Added Sugars	**4%**
Protein 3g	**23%**
Vitamin D 0mcg	0%
Calcium 35mg	6%
Iron 0.6mg	8%
Potassium 30mg	0%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 1,000 calories a day is used for general nutrition advice.

(B) [Reserved]

(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 processed, labeled, or repacked at a site other than where originally processed or packed.

(10) Raw fruits, vegetables, and fish subject to section 403(q)(4) of the act, except that the labeling of such foods should adhere to guidelines in § 101.45. This exemption is contingent on the food bearing 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 nutrition labeling in accordance with § 101.45. The term *fish* includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

(11) Packaged single-ingredient products that consist of fish or game meat (i.e., animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, or ostrich) subject to this section may provide required nutrition information for a 3-ounce cooked edible portion (i.e., on an ''as prepared'' basis), except that:

(i) Such products that make claims that are based on values as packaged must provide nutrition information on an as packaged basis, and

(ii) Nutrition information is not required for custom processed fish or game meats.

(12) Game meats (i.e., animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, or ostrich) may provide required nutrition information on labeling in accordance with the provisions of paragraph (a)(2) of this section.

(13)(i) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches, *Provided*, That the labels for these foods bear no nutrition claims or other nutrition information in any context on the label or in labeling or advertising, except as provided in § 101.8(c). Claims or other nutrition information, except as provided in § 101.8(c), subject the food to the provisions of this section.

(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)(2).

(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 for small packages.

Tabular Display for Small Packages

Nutrition Facts	Amount/serving	% DV*	Amount/serving	% DV*
5 servings per container	**Total Fat** 2g	**3%**	**Total Carb.** 15g	**5%**
Serving size 1/6 cup (28g)	Sat. Fat 1g	**5%**	Fiber 0g	**0%**
	Trans Fat 0.5g		Total Sugars 14g	
	Cholesterol 10mg	**3%**	Incl. 13g Added Sugars	**26%**
Calories per serving 90	**Sodium** 200mg	**9%**	**Protein** 3g	
	Vitamin D 0% • Calcium 6% • Iron 6% • Potassium 10%			

(*2*) The following sample label illustrates the linear display.

Linear Display for Small Packages

Nutrition Facts Servings: 12, **Serv. size: 1 mint (2g),**
Amount per serving: **Calories 5,** **Total Fat** 0g (0% DV), Sat. Fat 0g (0% DV), *Trans* Fat 0g, **Cholest.** 0mg (0% DV), **Sodium** 0mg (0% DV), **Total Carb.** 2g (1% DV), Fiber 0g (0% DV), Total Sugars 2g (Incl. 2g Added Sugars, 4% DV), **Protein** 0g.
Vit. D (0% DV), Calcium (0% DV), Iron (0% DV), Potas. (5% DV).

(B) Using any of the following abbreviations:

Serving size—Serv size
Servings per container—Servings
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. This abbreviation can also be used on dual-column displays as shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii).
Dietary fiber—Fiber
Soluble fiber—Sol fiber
Insoluble fiber—Insol fiber
Sugar alcohol—Sugar alc
Vitamin—Vit
Potassium—Potas
Includes—Incl. This abbreviation can also be used on dual-column displays as shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section.

(C) 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 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 Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., 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.

(l) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Office of Nutrition and Food Labeling (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2404 and is available from the sources indicated below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(1) AOAC Reseller. Techstreet, 6300 Interfirst Dr., Ann Arbor, MI 48108, Toll free in United States: 1–800–699–9277, Outside United States: 1–734–780–8000, Fax: 1–734–780–2046, *www.techstreet.com*, *techstreet.service@thomsonreuters.com*. FDA does not endorse any particular reseller and notes that other resellers also may have the reference for sale. Consult FDA at 240–402–2404 for more information on additional resellers.

(i) ''Official Methods of Analysis of the AOAC INTERNATIONAL,'' 19th Edition, Volumes 1 and 2, 2012.

(ii) [Reserved]

(2) Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO), Publications Division, Viale delle Terme di Caracalla, 00100 Rome, Italy

(i) FAO Food and Nutrition Paper 51,''Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' Rome, 1991. *http://apps.who.int/iris/bitstream/ 10665/38133/1/9251030979_eng.pdf*.

(ii) [Reserved]

(3) United States Department of Agriculture (USDA), Agricultural Research Service, Washington, DC, Nutrient Data Laboratory, Bldg. 005 Room 105 BARC-West, Beltsville, MD 20705, 301–504–0630. *http://www.ars.usda.gov/News/docs.htm?docid=9447*.

(i) USDA Handbook No. 74, Energy Value of Foods—basis and derivation, by A. L. Merrill and B. K. Watt, (slightly revised, 1973) *http://www.ars.usda.gov/SP2UserFiles/ Place/80400525/Data/Classics/ah74.pdf*.

(ii) [Reserved]

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EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 101.9, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 101.10 Nutrition labeling of restaurant foods whose labels or labeling bear nutrient content claims or health claims.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the nutrient amounts that are the basis for the claim (*e.g.*, ''low fat, this meal provides less than 10 grams of fat'') may serve as the functional equivalent of complete nutrition information as described in § 101.9. For the purposes of this section, restaurant food includes two categories of food. It includes food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments. It also includes food which is processed and prepared primarily in a retail establishment, which