

considered to be 100 percent juice and shall be declared as "100 percent juice."

(j) Calculations of the percentage of juice in a juice blend or a diluted juice product made directly from expressed juice (i.e., not from concentrate) shall be based on the percentage of the expressed juice in the product computed on a volume/volume basis.

(k) If the product is a beverage that contains a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable at the time processing is complete, or if its nutrient profile has been diminished to a level below the normal nutrient range for the juice, then that juice to which such a major modification has been made shall not be included in the total percentage juice declaration.

(l) A beverage required to bear a percentage juice declaration on its label, that contains less than 100 percent juice, shall not bear any other percentage declaration that describes the juice content of the beverage in its label or in its labeling (e.g., "100 percent natural" or "100 percent pure"). However, the label or labeling may bear percentage statements clearly unrelated to juice content (e.g., "provides 100 percent of U.S. RDA of vitamin C").

(m) Products purporting to be beverages that contain fruit or vegetable juices are exempted from the provisions of this section until May 8, 1994. All products that are labeled on or after that date shall comply with this section.

[58 FR 2925, Jan. 6, 1993, as amended at 58 FR 44063, Aug. 18, 1993; 58 FR 49192, Sept. 22, 1993]

### Subpart C—Specific Nutrition Labeling Requirements and Guidelines

SOURCE: 55 FR 60890, Nov. 27, 1991, unless otherwise noted.

#### § 101.36 Nutrition labeling of dietary supplements.

(a) The label of a dietary supplement that is offered for sale shall bear nutrition labeling in accordance with this regulation unless an exemption is provided for the product in paragraph (h) of this section.

(b) The declaration of nutrition information on the label and in labeling shall contain the following information, using the subheadings and the format specified in paragraph (e) of this section.

(1) *Serving size.* (i) The subheading "Serving Size" shall be placed under the heading "Supplement Facts" and aligned on the left side of the nutrition label. The serving size shall be determined in accordance with §§101.9(b) and 101.12(b), Table 2. Serving size for dietary supplements shall be expressed using a term that is appropriate for the form of the supplement, such as "tablets," "capsules," "packets," or "teaspoonfuls."

(ii) The subheading "Servings Per Container" shall be placed under the subheading "Serving Size" and aligned on the left side of the nutrition label, except that this information need not be provided when it is stated in the net quantity of contents declaration.

(2) *Information on dietary ingredients that have a Reference Daily Intake (RDI) or a Daily Reference Value (DRV) as established in §101.9(c) and their subcomponents (hereinafter referred to as "(b)(2)-dietary ingredients").* (i) The (b)(2)-dietary ingredients to be declared, that is, total calories, calories from fat, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with §101.9(c). Calories from saturated fat and polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugar alcohol, and other carbohydrate may be declared, but they shall be declared when a claim is made about them. Any other vitamins or minerals listed in §101.9(c)(8)(iv) or (c)(9) may be declared, but they shall be declared when they are added to the product for purposes of supplementation, or when a claim is made about them. Any (b)(2)-dietary ingredients that are not present, or that are present in amounts that can be declared as zero in §101.9(c), shall not be declared (e.g., amounts corresponding

to less than 2 percent of the RDI for vitamins and minerals). Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only individual amino acids.

(A) The names and the quantitative amounts by weight of each (b)(2)-dietary ingredient shall be presented under the heading “Amount Per Serving.” When the quantitative amounts by weight are presented in a separate column, the heading may be centered over a column of quantitative amounts, described by paragraph (b)(2)(ii) of this section, if space permits. A heading consistent with the declaration of the serving size, such as “Each Tablet Contains,” or “Amount Per 2 Tablets” may be used in place of the heading “Amount Per Serving.” Other appropriate terms, such as capsule, packet, or teaspoonful, also may be used in place of the term “Serving.”

(B) The names of dietary ingredients that are declared under paragraph (b)(2)(i) of this section shall be presented in a column aligned on the left side of the nutrition label in the order and manner of indentation specified in §101.9(c), except that calcium and iron shall follow pantothenic acid, and sodium and potassium shall follow chloride. This results in the following order for vitamins and minerals: Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B<sub>6</sub>, folate, vitamin B<sub>12</sub>, biotin, pantothenic acid, calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, and potassium. The (b)(2)-dietary ingredients shall be listed according to the nomenclature specified in §101.9 or in paragraph (b)(2)(i)(B)(2) of this section.

(1) When “Calories” are declared, they shall be listed first in the column of names, beneath a light bar separating the heading “Amount Per Serving” from the list of names. When “Calories from fat” or “Calories from saturated fat” are declared, they shall be indented beneath “Calories.”

(2) The following synonyms may be added in parentheses immediately following the name of these (b)(2)-dietary ingredients: Vitamin C (ascorbic acid), thiamin (vitamin B<sub>1</sub>), riboflavin (vita-

min B<sub>2</sub>), folate (folacin or folic acid), and calories (energy). Alternatively, the term “folic acid” or “folacin” may be listed without parentheses in place of “folate.” Energy content per serving may be expressed in kilojoule units, added in parentheses immediately following the statement of caloric content.

(3) Beta-carotene may be declared as the percent of vitamin A that is present as beta-carotene, except that the declaration is required when a claim is made about beta-carotene. When declared, the percent shall be declared to the nearest whole percent, immediately adjacent to or beneath the name vitamin A (e.g., “Vitamin A (90% as beta-carotene)”). The amount of beta-carotene in terms of international units (IU) may be included in parentheses following the percent statement (e.g., “Vitamin A (90% (4500 IU as beta-carotene)”).

(ii) The number of calories, if declared, and the quantitative amount by weight per serving of each dietary ingredient required to be listed under paragraph (b)(2)(i) of this section shall be presented either in a separate column aligned to the right of the column of names or immediately following the listing of names within the same column. The quantitative amounts by weight shall represent the weight of the dietary ingredient rather than the weight of the source of the dietary ingredient (e.g., the weight of calcium rather than that of calcium carbonate).

(A) These amounts shall be expressed in the increments specified in §101.9(c)(1) through (c)(7), which includes increments for sodium and potassium.

(B) The amounts of vitamins and minerals, excluding sodium and potassium, 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 §101.9(c)(8)(iv), 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 (mg), but the quantitative

amount may be declared in tenths of a mg).

(iii) The percent of the Daily Value of all dietary ingredients declared under paragraph (b)(2)(i) of this section shall be listed, except that the percent for protein may be omitted as provided in §101.9(c)(7); no percent shall be given for subcomponents for which DRV's have not been established (e.g., sugars); and, for labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women, no percent shall be given for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, vitamin K, selenium, manganese, chromium, molybdenum, chloride, sodium, or potassium.

(A) When information on the percent of Daily Values is listed, this information shall be presented in one column aligned under the heading of "% Daily Value" and to the right of the column of amounts. The headings "% Daily Value (DV)," "% DV," "Percent Daily Value," or "Percent DV" may be substituted for "% Daily Value." The heading "% Daily Value" shall be placed on the same line as the heading "Amount Per Serving." When the acronym "DV" is unexplained in the heading and a footnote is required under (b)(2)(iii)(D), (b)(2)(iii)(F), or (b)(3)(iv) of this section, the footnote shall explain the acronym (e.g. "Daily Value (DV) not established").

(B) The percent of Daily Value shall be calculated by dividing the quantitative amount by weight of each (b)(2)-dietary ingredient by the RDI as established in §101.9(c)(8)(iv) or the DRV as established in §101.9(c)(9) for the specified dietary ingredient and multiplying by 100, except that the percent of Daily Value for protein, when present, shall be calculated as specified in §101.9(c)(7)(ii). The quantitative amount by weight of each dietary ingredient in this calculation shall be the unrounded amount, except that for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber, the quantitative amount by weight declared on the label (i.e. rounded amount) may be used. The numerical value shall be followed by the symbol for percent (i.e., %).

(C) The percentages based on RDI's and on DRV's shall be expressed to the nearest whole percent, except that for dietary ingredients for which DRV's have been established, "Less than 1%" or "<1%" shall be used to declare the "% Daily Value" when the quantitative amount of the dietary ingredient by weight is great enough to require that the dietary ingredient be listed, but the amount is so small that the "% Daily Value" when rounded to the nearest percent is zero (e.g., a product that contains 1 gram of total carbohydrate would list the percent Daily Value as "Less than 1%" or "<1%").

(D) If the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement "Percent Daily Values are based on a 2,000 calorie diet."

(E) The percent of Daily Value shall be based on RDI and DRV values for adults and children 4 or more years of age, unless the product is represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women, in which case the column heading shall clearly state the intended group. If the product is for persons within more than one group, the percent of Daily Value for each group shall be presented in separate columns as shown in paragraph (e)(10)(ii) of this section.

(F) For declared subcomponents that have no DRV's and, on the labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women, for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, vitamin K, selenium, manganese, chromium, molybdenum, chloride, sodium, or potassium, a symbol (e.g., an asterisk) shall be placed in the "Percent Daily Value" column that shall refer to the same symbol that is placed at the bottom of the nutrition label, below the last

heavy bar and inside the box, and followed by the statement “Daily Value not established.”

(G) When calories, calories from fat, or calories from saturated fat are declared, the space under the “% Daily Value” column shall be left blank for these items. When there are no other (b)(2)-dietary ingredients listed for which a value must be declared in the “% Daily Value” column, the column may be omitted as shown in paragraph (e)(10)(vii) of this section. When the “% Daily Value” column is not required, but the dietary ingredients listed are subject to paragraph (b)(2)(iii)(F) of this section, the symbol required in that paragraph shall immediately follow the quantitative amount by weight for each dietary ingredient listed under “Amount Per Serving.”

(3) *Information on dietary ingredients for which RDI's and DRV's have not been established.* (i) Dietary ingredients for which FDA has not established RDI's or DRV's and that are not subject to regulation under paragraph (b)(2) of this section (hereinafter referred to as “other dietary ingredients”) shall be declared by their common or usual name when they are present in a dietary supplement, in a column that is under the column of names described in paragraph (b)(2)(i)(B) of this section or, as long as the constituents of an other dietary ingredient are not listed, in a linear display, under the heavy bar described in paragraph (e)(6) of this section, except that if no (b)(2)-dietary ingredients are declared, other dietary ingredients shall be declared directly beneath the heading “Amount Per Serving” described in paragraph (b)(2)(i)(A) of this section.

(ii) The quantitative amount by weight per serving of other dietary ingredients shall be presented in the same manner as the corresponding information required in paragraph (b)(2)(ii) of this section or, when a linear display is used, shall be presented immediately following the name of the other dietary ingredient. The quantitative amount by weight shall be the weight of the other dietary ingredient listed and not the weight of any component, or the source, of that dietary ingredient.

(A) These amounts shall be expressed using metric measures in appropriate units (i.e., 1,000 or more units shall be declared in the next higher set of units, e.g., 1,100 mg shall be declared as 1.1 g).

(B) For any dietary ingredient that is a liquid extract from which the solvent has not been removed, the quantity listed shall be the volume or weight of the total extract. Information on the condition of the starting material shall be indicated when it is fresh and may be indicated when it is dried. Information may be included on the concentration of the dietary ingredient and the solvent used, e.g., “fresh dandelion root extract, x (y:z) in 70% ethanol,” where x is the number of milliliters (mL) or mg of the entire extract, y is the weight of the starting material and z is the volume (mL) of solvent. Where the solvent has been partially removed (not to dryness), the final concentration, when indicated, shall be stated (e.g., if the original extract was 1:5 and 50 percent of the solvent was removed, then the final concentration shall be stated as 1:2.5). Where the name of the solvent used is not included in the nutrition label, it is required to be listed in the ingredient statement in accordance with §101.4(g).

(C) For a dietary ingredient that is an extract from which the solvent has been removed, the weight of the ingredient shall be the weight of the dried extract.

(iii) The constituents of a dietary ingredient described in paragraph (b)(3)(i) of this section may be listed indented under the dietary ingredient and followed by their quantitative amounts by weight per serving, except that dietary ingredients described in paragraph (b)(2) of this section shall be listed in accordance with that section. When the constituents of a dietary ingredient described in paragraph (b)(3)(i) of this section are listed, all other dietary ingredients shall be declared in a column; however, the constituents themselves may be declared in a column or in a linear display.

(iv) Other dietary ingredients shall bear a symbol (e.g., an asterisk) in the column under the heading of “% Daily Value” that refers to the same symbol placed at the bottom of the nutrition label and followed by the statement

“Daily Value not established,” except that when the heading “% Daily Value” is not used, the symbol shall follow the quantitative amount by weight for each dietary ingredient listed.

(c) A proprietary blend of dietary ingredients shall be included in the list of dietary ingredients described in paragraph (b)(3)(i) of this section and identified by the term “Proprietary Blend” or other appropriately descriptive term or fanciful name and may be highlighted by bold type. Except as specified in this paragraph, all other requirements for the listing of dietary ingredients in dietary supplements are applicable.

(1) Dietary ingredients contained in the proprietary blend that are listed under paragraph (b)(2) of this section shall be declared in accordance with paragraph (b)(2) of this section.

(2) Dietary ingredients contained in the proprietary blend that are listed under paragraph (b)(3) of this section (i.e., “other dietary ingredients”) shall be declared in descending order of predominance by weight, in a column or linear fashion, and indented under the term “Proprietary Blend” or other appropriately descriptive term or fanciful name.

(3) The quantitative amount by weight specified for the proprietary blend shall be the total weight of all other dietary ingredients contained in the proprietary blend and shall be placed on the same line to the right of the term “Proprietary Blend” or other appropriately descriptive term or fanciful name underneath the column of amounts described in paragraph (b)(2)(ii) of this section. A symbol (e.g., asterisk), which refers to the same symbol placed at the bottom of the nutrition label that is followed by the statement “Daily Value not established,” shall be placed under the heading “% Daily Value,” if present, or immediately following the quantitative amount by weight for the proprietary blend.

(4) The sample label shown in paragraph (e)(10)(v) of this section illustrates one method of nutrition labeling a proprietary blend of dietary ingredients.

(d) The source ingredient that supplies a dietary ingredient may be identified within the nutrition label in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the words “as” or “from”, e.g., “Calcium (as calcium carbonate),” except that manner of presentation is unnecessary when the name of the dietary ingredient (e.g., Oriental ginseng) or its synonym (e.g., ascorbic acid) is itself the source ingredient. When a source ingredient is identified in parentheses within the nutrition label, or when the name of the dietary ingredient or its synonym is the source ingredient, it shall not be required to be listed again in the ingredient statement that appears outside of the nutrition label. When a source ingredient is not identified within the nutrition label, it shall be listed in an ingredient statement in accordance with §101.4(g), which shall appear outside and immediately below the nutrition label or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label.

(1) Source ingredients shall be identified in accordance with §101.4 (i.e., shall be listed by common or usual name, and the listing of botanicals shall specify the part of the plant from which the ingredient is derived) regardless of whether they are listed in an ingredient statement or in the nutrition label.

(2) When source ingredients are listed within the nutrition label, and two or more are used to provide a single dietary ingredient, all of the sources shall be listed within the parentheses in descending order by weight.

(3) Representations that the source ingredient conforms to an official compendium may be included either in the nutrition label or in the ingredient list (e.g., “Calcium (as calcium carbonate USP)”).

(e) Nutrition information specified in this section shall be presented as follows:

(1) The title, “Supplement Facts,” shall be set in a type size larger than all other print size in the nutrition label and, unless impractical, shall be set full width of the nutrition label. The title and all headings shall be

bolded to distinguish them from other information.

(2) The nutrition information shall be enclosed in a box by using hairlines.

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

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

(ii) All black or one color type, printed on a white or other neutral contrasting background whenever practical,

(iii) Upper- and lowercase letters, except that all uppercase lettering may be utilized for packages that have a total surface area available to bear labeling of less than 12 square inches,

(iv) At least one point leading (i.e., space between lines of text), and

(v) Letters that do not touch.

(4) Except as provided for small and intermediate-sized packages under paragraph (i)(2) of this section, information other than the title, headings, and footnotes shall be in uniform type size no smaller than 8 point. Type size no smaller than 6 point may be used for column headings (e.g., “Amount Per Serving” and “% Daily Value”) and for footnotes (e.g., “Percent Daily Values are based on a 2,000 calorie diet”).

(5) A hairline rule that is centered between the lines of text shall separate each dietary ingredient required in paragraph (b)(2) and (b)(3) of this section from the dietary ingredient above and beneath it, as shown in paragraph (e)(10) of this section.

(6) A heavy bar shall be placed:

(i) Beneath the subheading “Servings Per Container” except that if “Servings Per Container” is not required and, as a result, not declared, the bar shall be placed beneath the subheading “Serving Size,”

(ii) Beneath the last dietary ingredient to be listed under paragraph (b)(2)(i) of this section, if any, and

(iii) Beneath the last other dietary ingredient to be listed under paragraph (b)(3) of this section, if any.

(7) A light bar shall be placed beneath the headings “Amount Per Serving” and “% Daily Value.”

(8) If the product contains two or more separately packaged dietary supplements that differ from each other (e.g., the product has a packet of supplements to be taken in the morning and a different packet to be taken in

the afternoon), the quantitative amounts and percent of Daily Value may be presented as specified in this paragraph in individual nutrition labels or in one aggregate nutrition label as illustrated in paragraph (e)(10)(iii) of this section.

(9)(i) The quantitative amount by weight (or volume, if permitted) and the percent of Daily Value of each dietary ingredient may be presented on a “per unit” basis in addition to the “per serving” basis required by paragraphs (b)(2)(ii) and (b)(2)(iii) of this section for (b)(2)-dietary ingredients and (b)(3)(ii) and (b)(3)(iv) of this section for other dietary ingredients. If “per unit” information is provided, it must be presented in additional columns to the right of the “per serving” information and be clearly identified by appropriate headings.

(ii) Alternatively, if a recommendation is made in other parts of the label that a dietary supplement be consumed more than once per day, the total quantitative amount by weight (or volume, if permitted) and the percent of Daily Value of each dietary ingredient may be presented on a “per day” basis in addition to the “per serving” basis required by paragraphs (b)(2)(ii) and (b)(2)(iii) of this section for (b)(2)-dietary ingredients and (b)(3)(ii) and (b)(3)(iv) of this section for other dietary ingredients. If “per day” information is provided, it must be presented in additional columns to the right of the “per serving” information and be clearly identified by appropriate headings and/or be presented in a parenthetical statement as part of the “Serving Size” declaration. A sample illustration for “per day” information in a column format is provided in paragraph (e)(11)(viii) of this section. As illustrated, the additional “Per Day” column heading is followed parenthetically by the number of servings recommended per day in other parts of the label (e.g., “Per Day (3 Caplets)”). When the parenthetical statement format following the “Serving Size” declaration is used as an alternative to the column format, the statement must provide no more than simple instructions regarding how to calculate the “per day” amount for the number of servings per day recommended in

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other parts of the label (e.g., “Serving Size: 1 Caplet (Multiply amounts by 3 for total daily amount)”). When the parenthetical statement format following the “Serving Size” declaration is used in addition to the column format, the statement must provide no more than a simple declaration of the number of servings recommended in other parts of the label (e.g., “Serving

Size: 1 Caplet (Total daily amount: 3 caplets per day)”).

(10) In the interest of uniformity of presentation, FDA urges that the information be presented using the graphic specifications set forth in appendix B to part 101, as applicable.

(11) The following sample labels are presented for the purpose of illustration:

(i) Multiple vitamins:

<b>Supplement Facts</b>		
Serving Size 1 Tablet		
	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	5000 IU	100%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D (as cholecalciferol)	400 IU	100%
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU	100%
Thiamin (as thiamin mononitrate)	1.5 mg	100%
Riboflavin	1.7 mg	100%
Niacin (as niacinamide)	20 mg	100%
Vitamin B <sub>6</sub> (as pyridoxine hydrochloride)	2.0 mg	100%
Folate (as folic acid)	400 mcg	100%
Vitamin B <sub>12</sub> (as cyanocobalamin)	6 mcg	100%
Biotin	30 mcg	10%
Pantothenic Acid (as calcium pantothenate)	10 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, propylparaben, and sodium benzoate.

(ii) Multiple vitamins for children and adults:

<b>Supplement Facts</b>			
Serving Size 1 Tablet			
Amount Per Serving		% Daily Value for Children Under 4 Years of Age	% Daily Value for Adults and Children 4 or more Years of Age
Calories	5		
Total Carbohydrate	1 g	†	< 1%*
Sugars	1 g	†	†
Vitamin A (50% as beta-carotene)	2500 IU	100%	50%
Vitamin C	40 mg	100%	67%
Vitamin D	400 IU	100%	100%
Vitamin E	15 IU	150%	50%
Thiamin	1.1 mg	157%	73%
Riboflavin	1.2 mg	150%	71%
Niacin	14 mg	156%	70%
Vitamin B <sub>6</sub>	1.1 mg	157%	55%
Folate	300 mcg	150%	75%
Vitamin B <sub>12</sub>	5 mcg	167%	83%

\* Percent Daily Values are based on a 2,000 calorie diet.  
 † Daily Value not established.

Other ingredients: Sucrose, sodium ascorbate, stearic acid, gelatin, maltodextrins, artificial flavors, dl-alpha tocopheryl acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, beta-carotene, folic acid, cholecalciferol, and cyanocobalamin.

(iii) Multiple vitamins in packets:

<b>Supplement Facts</b>				
Serving Size 1 Packet				
Servings Per Container 10				
	<b>AM Packet</b>		<b>PM Packet</b>	
<b>Amount Per Serving</b>	<b>% Daily Value</b>		<b>% Daily Value</b>	
Vitamin A	2500 IU	50%	2500 IU	50%
Vitamin C	60 mg	100%	60 mg	100%
Vitamin D	400 IU	100%		
Vitamin E	30 IU	100%		
Thiamin	1.5 mg	100%	1.5 mg	100%
Riboflavin	1.7 mg	100%	1.7 mg	100%
Niacin	20 mg	100%	20 mg	100%
Vitamin B <sub>6</sub>	2.0 mg	100%	2.0 mg	100%
Folic Acid	200 mcg	50%	200 mcg	50%
Vitamin B <sub>12</sub>	3 mcg	50%	3 mcg	50%
Biotin			30 mcg	10%
Pantothenic Acid	5 mg	50%	5 mg	50%

Ingredients: Sodium ascorbate, ascorbic acid, calcium pantothenate, niacinamide, dl-alpha tocopheryl acetate, microcrystalline cellulose, artificial flavors, dextrin, starch, mono- and diglycerides, vitamin A acetate, magnesium stearate, gelatin, FD&C Blue #1, FD&C Red #3, artificial colors, thiamin mononitrate, pyridoxine hydrochloride, citric acid, lactose, sorbic acid, tricalcium phosphate, sodium benzoate, sodium caseinate, methylparaben, potassium sorbate, BHA, BHT, ergocalciferol and cyanocobalamin.

- (iv) Dietary supplement containing dietary ingredient with and without RDI's and DRV's:

<b>Supplement Facts</b>		
Serving Size 1 Capsule		
Amount Per Capsule		% Daily Value
Calories	20	
Calories from Fat 20		
Total Fat	2 g	3%*
Saturated Fat	0.5 g	3%*
Polyunsaturated Fat	1 g	†
Monounsaturated Fat	0.5 g	†
Vitamin A	4250 IU	85%
Vitamin D	425 IU	106%
Omega-3 fatty acids	0.5 g	†

\* Percent Daily Values are based on a 2,000 calorie diet.  
 † Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

- (v) A proprietary blend of dietary ingredients:

<b>Supplement Facts</b>		
Serving Size 1 tsp (3 g) (makes 8 fl oz prepared)		
Servings Per Container 24		
	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	< 1%*
Sugars	2 g	†
Proprietary blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaves)		†

\* Percent Daily Values are based on a 2,000 calorie diet.  
 † Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

(vi) Dietary supplement of an herb

<b>Supplement Facts</b>	
Serving Size 1 Capsule	
Amount Per Capsule	
Oriental Ginseng, powdered (root)	250 mcg*
* Daily Value not established.	

Other ingredients: Gelatin, water, and glycerin.

(vii) Dietary supplement of amino acids:

<b>Supplement Facts</b>	
Serving Size 1 Tablet	
Amount Per Tablet	
Calories	15
Isoleucine (as L-isoleucine hydrochloride)	450 mg*
Leucine (as L-leucine hydrochloride)	620 mg*
Lysine (as L-lysine hydrochloride)	500 mg*
Methionine (as L-methionine hydrochloride)	350 mg*
Cystine (as L-cystine hydrochloride)	200 mg*
Phenylalanine (as L-phenylalanine hydrochloride)	220 mg*
Tyrosine (as L-tyrosine hydrochloride)	900 mg*
Threonine (as L-threonine hydrochloride)	300 mg*
Valine (as L-valine hydrochloride)	650 mg*
* Daily Value not established.	

Other ingredients: Cellulose, lactose, and magnesium stearate.

(viii) Dietary supplement illustrating “per serving” and “per day” information:

<b>Supplement Facts</b>				
<b>Serving Size 1 Caplet</b>				
	<b>Per Caplet</b>		<b>Per Day (3 Caplets)</b>	
	<b>Amount</b>	<b>% Daily Value</b>	<b>Amount</b>	<b>% Daily Value</b>
<b>Calcium (as calcium citrate)</b>	<b>500 mg</b>	<b>50%</b>	<b>1500 mg</b>	<b>150%</b>
<b>Vitamin D (as cholecalciferol)</b>	<b>125 IU</b>	<b>31%</b>	<b>375 IU</b>	<b>93%</b>

(12) If space is not adequate to list the required information as shown in the sample labels in paragraph (e)(11) of this section, the list may be split and continued to the right as long as the headings are repeated. The list to

the right must be set off by a line that distinguishes it and sets it apart from the dietary ingredients and percent of Daily Value information given to the left. The following sample label illustrates this display:

# Supplement Facts

Serving Size 1 Packet

Amount Per Packet	% Daily Value	Amount Per Packet	% Daily Value
Vitamin A (from cod liver oil)	5,000 IU	Zinc (as zinc oxide)	15 mg
Vitamin C (as ascorbic acid)	250 mg	Selenium (as sodium selenate)	25 mcg
Vitamin D (as ergocalciferol)	400 IU	Copper (as cupric oxide)	1 mg
Vitamin E (as d-alpha tocopherol)	150 IU	Manganese (as manganese sulfate)	5 mg
Thiamin (as thiamin mononitrate)	75 mg	Chromium (as chromium chloride)	50 mcg
Riboflavin	75 mg	Molybdenum (as sodium molybdate)	50 mcg
Niacin (as niacinamide)	75 mg	Potassium (as potassium chloride)	10 mg
Vitamin B <sub>6</sub> (as pyridoxine hydrochloride)	75 mg	Choline (as choline chloride)	100 mg
Folic Acid	400 mcg	Betaine (as betaine hydrochloride)	25 mg
Vitamin B <sub>12</sub> (as cyanocobalamin)	100 mcg	Glutamic Acid (as L-glutamic acid)	25 mg
Biotin	100 mcg	Inositol (as inositol monophosphate)	75 mg
Pantothenic Acid (as calcium pantothenate)	75 mg	<i>para</i> -Aminobenzoic acid	30 mg
Calcium (from oystershell)	100 mg	Deoxyribonucleic acid	50 mg
Iron (as ferrous fumarate)	10 mg	Boron	500 mcg
Iodine (from kelp)	150 mcg		
Magnesium (as magnesium oxide)	60 mg		

\* Daily Value not established

Other ingredients: Cellulose, stearic acid and silica.

(f)(1) Compliance with this section will be determined in accordance with §101.9(g)(1) through (g)(8), except that the sample for analysis shall consist of

a composite of 12 subsamples (consumer packages) or 10 percent of the

number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot. The criteria on class I and class II nutrients given in §101.9(g)(3) and (g)(4) also are applicable to other dietary ingredients described in paragraph (b)(3)(i) of this section. Reasonable excesses of these other dietary ingredients over labeled amounts are acceptable within current good manufacturing practice.

(2) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section, FDA may permit alternative means of compliance or additional exemptions to deal with the situation in accordance with §101.9(g)(9). Firms in need of such special allowances shall make their request in writing to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

(g) Except as provided in paragraphs (i)(2) and (i)(5) of this section, the location of nutrition information on a label shall be in compliance with §101.2.

(h) Dietary supplements are subject to the exemptions specified as follows in:

(1) Section 101.9(j)(1) for foods that are offered for sale by a person who makes direct sales to consumers (i.e., a retailer) who has annual gross sales 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, and whose labels, labeling, and advertising do not provide nutrition information or make a nutrient content or health claim;

(2) Section 101.9(j)(18) for foods that are low-volume products (that is, they meet the requirements for units sold in §101.9(j)(18)(i) or (j)(18)(ii)); that, except as provided in §101.9(j)(18)(iv), are the subject of a claim for an exemption that provides the information required under §101.9(j)(18)(iv), 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 ex-

emption under the requirements for average full-time equivalent employees in §101.9(j)(18)(i) or (j)(18)(ii), and whose labels, labeling, and advertising do not provide nutrition information or make a nutrient content or health claim;

(3) Section 101.9(j)(9) for foods 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 dietary supplements or that are to be processed, labeled, or repacked at a site other than where originally processed or packed.

(i) Dietary supplements are subject to the special labeling provisions specified in:

(1) Section 101.9(j)(5)(i) for foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age, in that nutrition labels on such foods shall not include calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol;

(2) Section 101.9(j)(13) for foods in small or intermediate-sized packages, except that:

(i) All information within the nutrition label on small-sized packages, which have a total surface area available to labeling of less than 12 square inches, shall be in type size no smaller than 4.5 point;

(ii) All information within the nutrition label on intermediate-sized packages, which have from 12 to 40 square inches of surface area available to bear labeling, shall be in type size no smaller than 6 point, except that type size no smaller than 4.5 point may be used on packages that have less than 20 square inches available for labeling and more than 8 dietary ingredients to be listed and on packages that have 20 to 40 square inches available for labeling and more than 16 dietary ingredients to be listed.

(iii) When the nutrition information is presented on any panel under §101.9(j)(13)(ii)(D), the ingredient list shall continue to be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label as specified in §101.4(g).

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

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

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

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

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

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

[62 FR 49849, Sept. 23, 1997, as amended at 63 FR 30620, June 5, 1998; 66 FR 56035, Nov. 6, 2001; 71 FR 51726, Aug. 31, 2006; 71 FR 74791, Dec. 13, 2006]

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

(a) The Food and Drug Administration (FDA) urges food retailers to provide nutrition information, as provided

in §101.9(c), for raw fruit, vegetables, and fish at the point-of-purchase. If retailers choose to provide such information, they should do so in a manner that conforms to the guidelines in §101.45.

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

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

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

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

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

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

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

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

(a) The Food and Drug Administration (FDA) will judge a food retailer who sells raw agricultural commodities or raw fish to be in compliance with the guidelines in § 101.45 with respect to raw agricultural commodities if the retailer displays or provides nutrition labeling for at least 90 percent of the raw agricultural commodities listed in § 101.44 that it sells, and with respect to raw fish if the retailer displays or provides nutrition labeling for at least 90 percent of the types of raw fish listed in § 101.44 that it sells. To be in compliance, the nutrition labeling shall:

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

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

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

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

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

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

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

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

(a) The 20 most frequently consumed raw fruits are: Apple, avocado (California), banana, cantaloupe, grapefruit, grapes, honeydew melon, kiwifruit, lemon, lime, nectarine, orange, peach,

pear, pineapple, plums, strawberries, sweet cherries, tangerine, and watermelon.

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

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

[71 FR 42044, July 25, 2006]

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

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

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

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

(3) When nutrition labeling information is provided for more than one raw fruit, vegetable, or fish on signs, posters, brochures, notebooks, or leaflets, it may be presented in charts with horizontal or vertical columns or as a compilation of individual nutrition labels. Nutrition labeling that is presented in a linear display (see

§101.9(j)(13)(ii)(A)(2)) will not be considered to be in compliance. The heading “Nutrition Facts” must be in a type size larger than all other print in the nutrition label. The required information (i.e., headings, serving sizes, list of nutrients, quantitative amounts by weight (except for vitamins and minerals), and percent of Daily Values (DV’s) (except for sugars and protein) must be clearly presented and of sufficient type size and color contrast to be plainly legible, with numeric values for percent of DV highlighted in contrast to the quantitative amounts by weight and hairlines between all nutrients.

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

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

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

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

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

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

(1) The agency encourages the submission of data bases with new or additional nutrient data for any of the most frequently consumed raw fruits, vegetables, and fish to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, for review and evaluation. FDA may incorporate these data in the next revision of the nutrition labeling information for the top 20 raw fruits, vegetables, and fish.

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

(ii) The submission to FDA should include, but need not be limited to, information on the following: Source of the data (names of investigators, name of organization, place of analyses, dates of analyses), number of samples, sampling design, analytical methods, and statistical treatment of the data. Proposed quantitative label declarations may be included. The proposed values for declaration should be determined in

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accordance with the “FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases.”

(2) [Reserved]

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

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

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

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

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

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

(B) FDA approval of a data base and nutrition labeling values shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the data base in writing. Approvals will be in effect for a limited time, e.g., 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices (e.g., a change occurs in a predominant variety produced). FDA will take steps to revoke its approval of the data base and nutri-

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tion labeling values if FDA monitoring suggests that the data base or nutrition labeling values are no longer representative of the item sold in this country. Approval requests shall be submitted in accordance with the provision of §101.30 of this chapter.

(ii) [Reserved]

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

### Subpart D—Specific Requirements for Nutrient Content Claims

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

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

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

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in §101.13; and

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

(b) *“High” claims.* (1) The terms “high,” “rich in,” or “excellent source of” may be used on the label and in the labeling of foods, except meal products as defined in §101.13(1) and main dish products as defined in §101.13(m), provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label and in the labeling of meal products as defined in §101.13(1) and main dish products as defined in §101.13(m), provided that:

(i) The product contains a food that meets the definition of “high” in paragraph (b)(1) of this section; and