

Attachment C

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 101_FOOD LABELING--Table of Contents

Subpart C_Specific Nutrition Labeling Requirements and Guidelines

Sec. 101.36 Nutrition labeling of dietary supplements.

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

(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.

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(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 Sec. Sec. 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 Sec. 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 Sec.

101.9(c) of this part.

(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 Sec. 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 B6, folate, vitamin B12, 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 Sec. 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 B1), riboflavin (vitamin B2), 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

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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 Sec. 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 Sec. 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 Sec. 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 Sec. 101.9(c)(8)(iv) or the DRV as established in Sec. 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 Sec. 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

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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.''

(iv) The quantitative amount by weight and the percent of Daily Value may be presented on a ``per unit'' basis in addition to on a ``per serving'' basis, as required in paragraph (b)(2)(ii) of this section. This information shall be presented in additional columns and clearly identified by appropriate headings.

(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

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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 Sec. 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.