

* * * * *

6. Section 101.36 is revised to read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

(a) The label of a dietary supplement 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, 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 in § 101.9(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." The heading may be centered over the column of quantitative amounts, described by paragraph (b)(2)(ii) of this section, if space permits. When the serving size of the product is one unit (e.g., one tablet), a heading consistent with the declaration of the serving size, such as "Amount Per Tablet" or "Each Tablet Contains," 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 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 § 101.9.

(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). Energy content per serving may be expressed in kilojoules 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 in a separate column aligned to the right of the column of names. 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 actual 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, sodium, potassium, vitamin K, chloride, chromium, manganese, molybdenum, or selenium.

(A) When information on the percent of Daily Values is listed, this