

§ 101.30

21 CFR Ch. I (4–1–11 Edition)

such certification or to show a potential or actual violation may be removed or transmitted from the certifying party's place of business: *Provided*, That, where such removal or transmittal is necessary for such purposes the relevant records and notes shall be retained as separate documents in Food and Drug Administration files, shall not be copied in other reports, and shall not be disclosed publicly other than in a judicial proceeding brought pursuant to the act or 18 U.S.C. 1001.

(j) A food to which a chemical preservative(s) is added shall, except when exempt pursuant to §101.100 bear a label declaration stating both the common or usual name of the ingredient(s) and a separate description of its function, e.g., "preservative", "to retard spoilage", "a mold inhibitor", "to help protect flavor" or "to promote color retention".

(k) The label of a food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section, except that colorings added to butter, cheese, and ice cream, if declared, may be declared in the manner specified in paragraph (k)(3) of this section, and colorings added to foods subject to §§105.62 and 105.65 of this chapter shall be declared in accordance with the requirements of those sections.

(1) A color additive or the lake of a color additive subject to certification under 721(c) of the act shall be declared by the name of the color additive listed in the applicable regulation in part 74 or part 82 of this chapter, except that it is not necessary to include the "FD&C" prefix or the term "No." in the declaration, but the term "Lake" shall be included in the declaration of the lake of the certified color additive (e.g., Blue 1 Lake). Manufacturers may parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name as specified in part 74 or part 82 of this chapter.

(2) Color additives not subject to certification and not otherwise required by applicable regulations in part 73 of this chapter to be declared by their respective common or usual names may

be declared as "Artificial Color," "Artificial Color Added," or "Color Added" (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as "Colored with _____" or "_____ color," the blank to be filled in with the name of the color additive listed in the applicable regulation in part 73 of this chapter.

(3) When a coloring has been added to butter, cheese, or ice cream, it need not be declared in the ingredient list unless such declaration is required by a regulation in part 73 or part 74 of this chapter to ensure safe conditions of use for the color additive. Voluntary declaration of all colorings added to butter, cheese, and ice cream, however, is recommended.

[42 FR 14308, Mar. 15, 1977, as amended at 44 FR 3963, Jan. 19, 1979; 44 FR 37220, June 26, 1979; 54 FR 24891, June 12, 1989; 58 FR 2875, Jan. 6, 1993; 63 FR 14818, Mar. 27, 1998; 74 FR 216, Jan. 5, 2009]

§ 101.30 Percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice.

(a) This section applies to any food that purports to be a beverage that contains any fruit or vegetable juice (i.e., the product's advertising, label, or labeling bears the name of, or variation on the name of, or makes any other direct or indirect representation with respect to, any fruit or vegetable juice), or the label or labeling bears any vignette (i.e., depiction of a fruit or vegetable) or other pictorial representation of any fruit or vegetable, or the product contains color and flavor that gives the beverage the appearance and taste of containing a fruit or vegetable juice. The beverage may be carbonated or noncarbonated, concentrated, full-strength, diluted, or contain no juice. For example, a soft drink (soda) that does not represent or suggest by its physical characteristics, name, labeling, ingredient statement, or advertising that it contains fruit or vegetable juice does not purport to contain juice and therefore does not require a percent juice declaration.

(b)(1) If the beverage contains fruit or vegetable juice, the percentage shall be declared by the words "Contains ___ percent (or %) _____ juice" or "___ percent (or %) juice," or a similar phrase, with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the juice and the second blank (if used) filled in with the name of the particular fruit or vegetable (e.g., "Contains 50 percent apple juice" or "50 percent juice").

(2) If the beverage contains less than 1 percent juice, the total percentage juice shall be declared as "less than 1 percent juice" or "less than 1 percent _____ juice" with the blank filled in with the name of the particular fruit or vegetable.

(3) If the beverage contains 100 percent juice and also contains non-juice ingredients that do not result in a diminution of the juice soluble solids or, in the case of expressed juice, in a change in the volume, when the 100 percent juice declaration appears on a panel of the label that does not also bear the ingredient statement, it must be accompanied by the phrase "with added _____," the blank filled in with a term such as "ingredient(s)," "preservative," or "sweetener," as appropriate (e.g., "100% juice with added sweetener"), except that when the presence of the non-juice ingredient(s) is declared as a part of the statement of identity of the product, this phrase need not accompany the 100 percent juice declaration.

(c) If a beverage contains minor amounts of juice for flavoring and is labeled with a flavor description using terms such as "flavor", "flavored", or "flavoring" with a fruit or vegetable name and does not bear:

(1) The term "juice" on the label other than in the ingredient statement; or

(2) An explicit vignette depicting the fruit or vegetable from which the flavor derives, such as juice exuding from a fruit or vegetable; or

(3) Specific physical resemblance to a juice or distinctive juice characteristic such as pulp then total percentage juice declaration is not required.

(d) If the beverage does not meet the criteria for exemption from total juice

percentage declaration as described in paragraph (c) of this section and contains no fruit or vegetable juice, but the labeling or color and flavor of the beverage represents, suggests, or implies that fruit or vegetable juice may be present (e.g., the product advertising or labeling bears the name, a variation of the name, or a pictorial representation of any fruit or vegetable, or the product contains color and flavor that give the beverage the appearance and taste of containing a fruit or vegetable juice), then the label shall declare "contains zero (0) percent (or %) juice". Alternatively, the label may declare "Containing (or contains) no _____ juice", or "no _____ juice", or "does not contain _____ juice", the blank to be filled in with the name of the fruits or vegetables represented, suggested, or implied, but if there is a general suggestion that the product contains fruit or vegetable juice, such as the presence of fruit pulp, the blank shall be filled in with the word "fruit" or "vegetable" as applicable (e.g., "contains no fruit juice", or "does not contain fruit juice").

(e) If the beverage is sold in a package with an information panel as defined in §101.2, the declaration of amount of juice shall be prominently placed on the information panel in lines generally parallel to other required information, appearing:

(1) Near the top of the information panel, with no other printed label information appearing above the statement except the brand name, product name, logo, or universal product code; and

(2) In easily legible boldface print or type in distinct contrast to other printed or graphic matter, in a height not less than the largest type found on the information panel except that used for the brand name, product name, logo, universal product code, or the title phrase "Nutrition Facts" appearing in the nutrition information as required by §101.9.

(f) The percentage juice declaration may also be placed on the principal display panel, provided that the declaration is consistent with that presented on the information panel.

(g) If the beverage is sold in a package that does not bear an information

§ 101.30

panel as defined in §101.2, the percentage juice declaration shall be placed on the principal display panel, in type size not less than that required for the declaration of net quantity of contents statement in §101.105(i), and be placed near the name of the food.

(h)(1) In enforcing these regulations, the Food and Drug Administration will calculate the labeled percentage of juice from concentrate found in a juice or juice beverage using the minimum Brix levels listed below where single-strength (100 percent) juice has at least the specified minimum Brix listed below:

Juice	100 percent juice ¹
Acerola	6.0
Apple	11.5
Apricot	11.7
Banana	22.0
Blackberry	10.0
Blueberry	10.0
Boysenberry	10.0
Cantaloupe Melon	9.6
Carambola	7.8
Carrot	8.0
Casaba Melon	7.5
Cashew (Caju)	12.0
Celery	3.1
Cherry, dark, sweet	20.0
Cherry, red, sour	14.0
Crabapple	15.4
Cranberry	7.5
Currant (Black)	11.0
Currant (Red)	10.5
Date	18.5
Dewberry	10.0
Elderberry	11.0
Fig	18.2
Gooseberry	8.3
Grape	16.0
Grapefruit	³ 10.0
Guanabana (soursop)	16.0
Guava	7.7
Honeydew melon	9.6
Kiwi	15.4
Lemon	² 4.5
Lime	² 4.5
Loganberry	10.5
Mango	13.0
Nectarine	11.8
Orange	³ 11.8
Papaya	11.5
Passion Fruit	14.0
Peach	10.5
Pear	12.0
Pineapple	12.8
Plum	14.3
Pomegranate	16.0
Prune	18.5
Quince	13.3
Raspberry (Black)	11.1
Raspberry (Red)	9.2
Rhubarb	5.7
Strawberry	8.0
Tangerine	³ 11.8
Tomato	5.0

21 CFR Ch. I (4–1–11 Edition)

Juice	100 percent juice ¹
Watermelon	7.8
Youngberry	10.0

¹ Indicates Brix value unless other value specified.

² Indicates anhydrous citrus acid percent by weight.

³ Brix values determined by refractometer for citrus juices may be corrected for citric acid.

(2) If there is no Brix level specified in paragraph (h)(1) of this section, the labeled percentage of that juice from concentrate in a juice or juice beverage will be calculated on the basis of the soluble solids content of the single-strength (unconcentrated) juice used to produce such concentrated juice.

(i) Juices directly expressed from a fruit or vegetable (i.e., not concentrated and reconstituted) shall be 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 di-

etary 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 B₆, folate, vitamin B₁₂, biotin,