

conformance with the provisions of paragraph (d) of this section.

3. Section 101.4 is amended by revising paragraph (a)(1) and adding new paragraphs (g) and (h) to read as follows:

§ 101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by § 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2, except that ingredients in dietary supplements that are listed in the nutrition label in accordance with § 101.36 need not be repeated in the ingredient list. Paragraph (g) of this section describes the ingredient list on dietary supplement products.

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(g) When present, the ingredient list on dietary supplement products shall 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 and shall be preceded by the word "Ingredients," unless some

ingredients (i.e., sources) are identified within the nutrition label in accordance with § 101.36(d), in which case the ingredients listed outside the nutrition label shall be in a list preceded by the words "Other Ingredients." Ingredients in dietary supplements that are not dietary ingredients or that do not contain dietary ingredients, such as excipients, fillers, artificial colors, artificial sweeteners, flavors, or binders, shall be included in the ingredient list.

(h) The common or usual name of ingredients of dietary supplements that are botanicals (including fungi and algae) shall be immediately followed by parenthetical statements of:

(1) The Latin binomial name of the plant. Any name in Latin form shall be in accordance with internationally accepted rules on nomenclature, such as those found in the *International Code of Botanical Nomenclature*, and shall include the designation of the author or authors who published the Latin name, when appropriate; and

(2) The part of the plant (e.g., root, leaves) from which the dietary ingredient is derived (e.g., "Garlic (*Allium sativum* L.) (bulb)"), except that this designation is not required for algae. The name of the part of the plant shall be expressed in English (e.g., "flower" rather than "flos").

(3) On labels of single-ingredient dietary supplements that do not include an ingredient list, the required identification of the Latin binomial name and the part of the plant may be prominently placed on the principal display panel or information panel, or included in the nutrition label.

4. Section 101.9 is amended by revising paragraph (j)(6), by removing paragraphs (k)(2) and (k)(5), and by redesignating paragraphs (k)(3), (k)(4), and (k)(6) as (k)(2), (k)(3), and (k)(4), respectively, to read as follows:

§ 101.9 Nutrition labeling of food.

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(j) * * *

(6) Dietary supplements, except that such foods shall be labeled in compliance with § 101.36.

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5. Section 101.12 is amended in paragraph (b), Table 2, by revising the entry "Dietary supplements not in conventional food form" under the subheading "Miscellaneous category" to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

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(b) * * *

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY^{1,2,3,4}

Product category	Reference amount	Label statement ⁵
* * * * *	* * * * *	* * * * *
Miscellaneous Category—		
* * * * *	* * * * *	* * * * *
Dietary supplements	The maximum amount recommended, as appropriate, on the label for consumption per eating occasion, or, in the absence of recommendations, 1 unit, e.g., tablet, capsule, packet, teaspoonful, etc.	_____ tablet(s) _____ capsule(s), _____ packet(s), tsp(s) (____g), etc.
* * * * *	* * * * *	* * * * *

¹ These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

² Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes; concentrates; dough; batter; dry, fresh, and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

³ Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

⁴ Copies of the list of products for each product category are available from the Office of Food Labeling (HFS–150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

⁵ The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term "piece" is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (e.g., dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 101.9(b) using the reference amount determined according to § 101.12(c).