

(f)(1) Compliance with this section will be determined in accordance with § 101.9 (g)(1) through (g)(8). 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 Food Labeling (HFS-150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(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 in:

(1) § 101.9(j)(1) for dietary supplements 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) § 101.9(j)(18) for dietary supplements that are low-volume products (that is, they meet the requirements for units sold in § 101.9(j)(18) (i) or (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 that qualifies to claim the exemption under the requirements for average full-time equivalent

employees in § 101.9(j)(18) (i) or (ii), and whose labels, labeling, and advertising do not provide nutrition information or make a nutrient content or health claim;

(3) § 101.9(j)(9) for dietary supplements 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) § 101.9(j)(5)(i) for food, 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) § 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 dietary supplements in which there are more than 8 dietary ingredients to be listed in the nutrition label, and that are in packages that have less than 20 square inches of surface area available to bear labeling, may use type size no smaller than 4.5 point when necessary.

(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.

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

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

(5) § 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).

7. Section 101.65 is amended by revising paragraph (b)(4) to read as follows:

§ 101.65 Implied Nutrient Content Claims and Related Label Statements.

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(b) * * *

(4) A statement of identity for a food in which an ingredient constitutes essentially 100 percent of a food (e.g., "corn oil," "oat bran," "dietary supplement of vitamin C 60 mg tablet").

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Dated: October 11, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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