

§ 101.42

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.

(v) Where there is not sufficient space on a small or intermediate-sized package for a nutrition label that meets minimum type size requirements of 4.5 points if hairlines are used in accordance with paragraph (e)(5) of this section, the hairlines may be omitted and replaced by a row of dots connecting the columns containing the name of each dietary ingredient and the quantitative amounts (by weight and as a percent of Daily Value).

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

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

(5) Section 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).

[62 FR 49849, Sept. 23, 1997, as amended at 63 FR 30620, June 5, 1998; 66 FR 56035, Nov. 6, 2001]

21 CFR Ch. I (4-1-04 Edition)

EFFECTIVE DATE NOTE: At 69 FR 41505, July 11, 2003, §101.36 was amended by revising paragraph (b)(2)(i), effective January 1, 2006. For the convenience of the user the revised text is set forth as follows:

§ 101.36 Nutrition labeling of dietary supplements.

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(b) * * *

(2) * * *

(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 §101.9(c) of this part. * * *

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§ 101.42 Nutrition labeling of raw fruit, vegetables, and fish.

(a) The Food and Drug Administration (FDA) urges food retailers to provide nutrition information, as provided in §101.9(c), for raw fruit, vegetables, and fish at the point-of-purchase. If retailers choose to provide such information, they should do so in a manner that conforms to the guidelines in §101.45.

(b) In §101.44, FDA has listed the 20 varieties of raw fruit, vegetables, and fish that are most frequently consumed during a year and to which the guidelines apply.

(c) FDA has also defined in §101.43, the circumstances that constitute substantial compliance by food retailers with the guidelines.

(d) By May 8, 1993, FDA will issue a report on actions taken by food retailers to provide consumers with nutrition information for raw fruit, vegetables, and fish under the guidelines established in §101.45.

(1) The report will include a determination of whether there is substantial compliance, as defined in §101.43, with the guidelines.

(2) In evaluating substantial compliance, FDA will consider only the 20 varieties of raw fruit, vegetables, and fish most frequently consumed as identified in §101.44.

(e) If FDA finds that there is substantial compliance with the guidelines for the nutrition labeling of raw fruit and vegetables or of fish, the agency will so state in the report, and the guidelines will remain in effect. FDA will reevaluate the market place for substantial compliance every 2 years.

(f) If FDA determines that there is not substantial compliance with the guidelines for raw fruit and vegetables or for raw fish, the agency will at that time issue proposed regulations requiring that any person who offers raw fruit and vegetables or fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by §101.9. Final regulations would have to be issued 6 months after issuance of proposed regulations, and they would become effective 6 months after the date of their promulgation.

§101.43 Substantial compliance of food retailers with the guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.

(a) The Food and Drug Administration (FDA) will judge a food retailer who sells raw agricultural commodities or raw fish to be in compliance with the guidelines in §101.45 with respect to raw agricultural commodities if the retailer displays or provides nutrition labeling for at least 90 percent of the raw agricultural commodities listed in §101.44 that it sells, and with respect to raw fish if the retailer displays or provides nutrition labeling for at least 90 percent of the types of raw fish listed in §101.44 that it sells. To be in compliance, the nutrition labeling shall:

(1) Be presented in the store or other type of establishment in a manner that is consistent with §101.45(a)(1);

(2) Be presented in content and format that are consistent with §101.45(a)(2), (a)(3), and (a)(4); and

(3) Include data that have been provided by FDA in appendices C and D to part 101 of this chapter, except that the information on potassium is voluntary.

(b) To determine whether there is substantial compliance by food retailers with the guidelines in §101.45 for the voluntary nutrition labeling of raw fruit and vegetables and of raw fish, FDA will select a representative sam-

ple of 2,000 stores, allocated by store type and size, for raw fruit and vegetables and for raw fish.

(c) FDA will find that there is substantial compliance with the guidelines in §101.45 if it finds based on paragraph (a) of this section that at least 60 percent of all stores that are evaluated are in compliance.

(d) FDA will evaluate substantial compliance separately for raw agricultural commodities and for raw fish.

[55 FR 60890, Nov. 27, 1991, as amended at 61 FR 42759, Aug. 16, 1996]

§101.44 Identification of the 20 most frequently consumed raw fruit, vegetables, and fish in the United States.

(a) The 20 most frequently consumed raw fruit are: Banana, apple, watermelon, orange, cantaloupe, grape, grapefruit, strawberry, peach, pear, nectarine, honeydew melon, plum, avocado, lemon, pineapple, tangerine, sweet cherry, kiwifruit, and lime.

(b) The 20 most frequently consumed raw vegetables are: Potato, iceberg lettuce, tomato, onion, carrot, celery, sweet corn, broccoli, green cabbage, cucumber, bell pepper, cauliflower, leaf lettuce, sweet potato, mushroom, green onion, green (snap) bean, radish, summer squash, and asparagus.

(c) The 20 most frequently consumed raw fish are: Shrimp, cod, pollock, catfish, scallops, salmon (Atlantic/Coho, chum/pink, sockeye), flounder/sole, oysters, orange roughy, Atlantic/Pacific mackerel, ocean perch, rockfish, whiting, clam, haddock, blue crab, rainbow trout, halibut, lobster, and swordfish.

[55 FR 60890, Nov. 27, 1991, as amended at 61 FR 42760, Aug. 16, 1996]

§101.45 Guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish.

(a) Nutrition labeling for raw fruits, vegetables, and fish listed in §101.44 should be presented to the public in the following manner:

(1) Nutrition labeling information should be displayed at the point of purchase by an appropriate means such as by a label affixed to the food or through labeling including shelf labels, signs, posters, brochures, notebooks, or