

per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount as defined in §101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the "as prepared" form);

(iii) The food contains at least 10 percent of the RDI or DRV per reference amount customarily consumed of vitamin A, vitamin C, calcium, iron, protein, or fiber;

(iv) Where compliance with paragraph (d)(3)(iii) of this section is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in §104.20 of this chapter; and

(v) The food complies with definitions and declaration requirements established in this part for any specific nutrient content claim on the label or in labeling.

(4) The term "healthy" or its derivatives may be used on the label or in labeling of main dish products, as defined in §101.13(m), and meal products, as defined in §101.13(l) as an implied nutrient content claim provided that:

(i) The food meets the definition of "low" for fat and saturated fat;

(ii)(A) Before January 1, 1998, sodium is not present at a level exceeding 600 mg per labeled serving, or

(B) After January 1, 1998, sodium is not present at a level exceeding 480 mg per labeled serving;

(iii) Cholesterol is not present at a level exceeding 90 mg per labeled serving;

(iv) The food contains at least 10 percent of the RDI or DRV per labeled serving of two (for main dish products) or three (for meal products) of the following nutrients—vitamin A, vitamin C, calcium, iron, protein, or fiber;

(v) Where compliance with paragraph (d)(4)(iv) of this section is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in §104.20 of this chapter; and

(vi) The food complies with definitions and declaration requirements established in this part for any specific

nutrient content claim on the label or in labeling.

[58 FR 2413, Jan. 6, 1993; 58 FR 17343, Apr. 2, 1993, as amended at 59 FR 394, Jan. 4, 1994; 59 FR 24249, May 10, 1994; 59 FR 50828, Oct. 6, 1994; 63 FR 14355, Mar. 25, 1998]

EFFECTIVE DATE NOTES: 1. At 59 FR 24249, May 10, 1994, §101.65 was amended by adding paragraphs (d) (2) through (4). At 62 FR 15391, Apr. 1, 1997, paragraphs (d) (2)(ii)(C) and (4)(ii)(B) were stayed until Jan. 1, 2000.

2. At 62 FR 49858, Sept. 23, 1997, §101.65 was amended by revising paragraph (b)(4), effective Mar. 23, 1999. For the convenience of the user, the revised text is set forth 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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§ 101.67 Use of nutrient content claims for butter.

(a) Claims may be made to characterize the level of nutrients, including fat, in butter if:

(1) The claim complies with the requirements of §101.13 and with the requirements of the regulations in this subpart that define the particular nutrient content claim that is used and how it is to be presented. In determining whether a claim is appropriate, the calculation of the percent fat reduction in milkfat shall be based on the 80 percent milkfat requirement provided by the statutory standard for butter (21 U.S.C. 321a);

(2) The product contains cream or milk, including milk constituents (including, but not limited to, whey, casein, modified whey, and salts of casein), or both, with or without added salt, with or without safe and suitable colorings, with or without nutrients added to comply with paragraph (a)(3) of this section, and with or without safe and suitable bacterial cultures. The product may contain safe and suitable ingredients to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add

sweetness. The product may contain water to replace milkfat although the amount of water in the product shall be less than the amount of cream, milk, or milk constituents;

(3) The product is not nutritionally inferior, as defined in §101.3(e)(4), to butter as produced under 21 U.S.C. 321a; and

(4) If the product would violate 21 U.S.C. 321a but for the nutrient content claim that characterizes the level of nutrients, that claim shall be an explicit claim that is included as part of the common or usual name of the product.

(b) Deviations from the ingredient provisions of 21 U.S.C. 321a must be the minimum necessary to achieve similar performance characteristics as butter as produced under 21 U.S.C. 321a, or the food will be deemed to be adulterated under section 402(b) of the act. The performance characteristics (e.g., physical properties, organoleptic characteristics, functional properties, shelf life) of the product shall be similar to butter as produced under 21 U.S.C. 321a. If there is a significant difference in performance characteristics (that materially limits the uses of the product compared to butter,) the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for baking purposes"). Such statement shall comply with the requirements of §101.13(d). The modified product shall perform at least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a.

(c)(1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of this part.

(2) Safe and suitable ingredients added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness and water added to replace milkfat shall be identified with an asterisk in the ingredient statement. The statement "**Ingredients not in regular butter" shall immediately follow the ingredient statement in the same type size.

[58 FR 2455, Jan. 6, 1993]

§ 101.69 Petitions for nutrient content claims.

(a) This section pertains to petitions for claims, expressed or implied, that:

(1) Characterize the level of any nutrient which is of the type required to be in the label or labeling of food by section 403(q)(1) or (q)(2) of the Federal Food, Drug, and Cosmetic Act (the act); and

(2) That are not exempted under section 403(r)(5)(A) through (r)(5)(C) of the act from the requirements for such claims in section 403(r)(2).

(b) Petitions included in this section are:

(1) Petitions for a new (heretofore unauthorized) nutrient content claim;

(2) Petitions for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient; and

(3) Petitions for the use of an implied claim in a brand name.

(c) An original and one copy of the petition to be filed under the provisions of section 403(r)(4) of the act shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. Petitioners interested in submitting a disk should contact FDA's Center for Food Safety and Applied Nutrition for details. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which published notices as required by section 403 of the act may be sent.

(d) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information