

(II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.

A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.

(t) Catfish

If it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae.

(u) Ginseng

If it purports to be or is represented as ginseng, unless it is an herb or herbal ingredient derived from a plant classified within the genus *Panax*.

(v) Failure to label; health threat

If—

(1) it fails to bear a label required by the Secretary under section 381(n)(1) of this title (relating to food refused admission into the United States);

(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

(3) upon or after notifying the owner or consignee involved that the label is required under section 381 of this title, the Secretary informs the owner or consignee that the food presents such a threat.

(w) Major food allergen labeling requirements

(1) If it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either—

(A) the word “Contains”, followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients (in a type size no smaller than the type size used in the list of ingredients) required under subsections (g) and (i); or

(B) the common or usual name of the major food allergen in the list of ingredients required under subsections (g) and (i) is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when—

(i) the common or usual name of the ingredient uses the name of the food source from which the major food allergen is derived; or

(ii) the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list, unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of a food ingredient that is not a major food allergen under section 321(qq)(2)(A) or (B) of this title.

(2) As used in this subsection, the term “name of the food source from which the major food allergen is derived” means the name described in section 321(qq)(1) of this title; provided that in the case of a tree nut, fish, or Crustacean shell-

fish, the term “name of the food source from which the major food allergen is derived” means the name of the specific type of nut or species of fish or Crustacean shellfish.

(3) The information required under this subsection may appear in labeling in lieu of appearing on the label only if the Secretary finds that such other labeling is sufficient to protect the public health. A finding by the Secretary under this paragraph (including any change in an earlier finding under this paragraph) is effective upon publication in the Federal Register as a notice.

(4) Notwithstanding subsection (g), (i), or (k), or any other law, a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen shall be subject to the labeling requirements of this subsection.

(5) The Secretary may by regulation modify the requirements of subparagraph (A) or (B) of paragraph (1), or eliminate either the requirement of subparagraph (A) or the requirements of subparagraph (B) of paragraph (1), if the Secretary determines that the modification or elimination of the requirement of subparagraph (A) or the requirements of subparagraph (B) is necessary to protect the public health.

(6)(A) Any person may petition the Secretary to exempt a food ingredient described in section 321(qq)(2) of this title from the allergen labeling requirements of this subsection.

(B) The Secretary shall approve or deny such petition within 180 days of receipt of the petition or the petition shall be deemed denied, unless an extension of time is mutually agreed upon by the Secretary and the petitioner.

(C) The burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.

(D) A determination regarding a petition under this paragraph shall constitute final agency action.

(E) The Secretary shall promptly post to a public site all petitions received under this paragraph within 14 days of receipt and the Secretary shall promptly post the Secretary’s response to each.

(7)(A) A person need not file a petition under paragraph (6) to exempt a food ingredient described in section 321(qq)(2) of this title from the allergen labeling requirements of this subsection, if the person files with the Secretary a notification containing—

(i) scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein; or

(ii) a determination by the Secretary that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 348 of this title.

(B) The food ingredient may be introduced or delivered for introduction into interstate commerce as a food ingredient that is not a major food allergen 90 days after the date of receipt of

the notification by the Secretary, unless the Secretary determines within the 90-day period that the notification does not meet the requirements of this paragraph, or there is insufficient scientific evidence to determine that the food ingredient does not contain allergenic protein or does not cause an allergenic response that poses a risk to human health.

(C) The Secretary shall promptly post to a public site all notifications received under this subparagraph within 14 days of receipt and promptly post any objections thereto by the Secretary.

(x) Nonmajor food allergen labeling requirements

Notwithstanding subsection (g), (i), or (k), or any other law, a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation.

(y) Dietary supplements

If it is a dietary supplement that is marketed in the United States, unless the label of such dietary supplement includes a domestic address or domestic phone number through which the responsible person (as described in section 379aa-1 of this title) may receive a report of a serious adverse event with such dietary supplement.

(June 25, 1938, ch. 675, § 403, 52 Stat. 1047; Pub. L. 86-537, § 1, June 29, 1960, 74 Stat. 251; Pub. L. 86-618, title I, § 102(a)(3), July 12, 1960, 74 Stat. 398; Pub. L. 91-601, § 6(c), formerly § 7(c), Dec. 30, 1970, 84 Stat. 1673, renumbered Pub. L. 97-35, title XII, § 1205(c), Aug. 13, 1981, 95 Stat. 716; Pub. L. 94-278, title V, § 502(a)(1), Apr. 22, 1976, 90 Stat. 411; Pub. L. 95-203, § 4(a)(1), (b)(1), Nov. 23, 1977, 91 Stat. 1452, 1453; Pub. L. 101-535, §§ 2(a), 3(a), 7, Nov. 8, 1990, 104 Stat. 2353, 2357, 2364; Pub. L. 102-108, § 2(a), (c), Aug. 17, 1991, 105 Stat. 549; Pub. L. 102-571, title I, § 107(5), (6), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103-80, §§ 2(b), 3(j), Aug. 13, 1993, 107 Stat. 773, 776; Pub. L. 103-417, §§ 6, 7(a)-(c), 10(c), Oct. 25, 1994, 108 Stat. 4329, 4330, 4332; Pub. L. 104-124, § 1, Apr. 1, 1996, 110 Stat. 882; Pub. L. 105-115, title III, §§ 301-305, Nov. 21, 1997, 111 Stat. 2350-2353; Pub. L. 106-554, § 1(a)(1) [title V, § 517], Dec. 21, 2000, 114 Stat. 2763, 2763A-73; Pub. L. 107-171, title X, §§ 10806(a)(2), (b)(2), 10808(b), May 13, 2002, 116 Stat. 526, 527, 530; Pub. L. 107-188, title III, § 308(b), June 12, 2002, 116 Stat. 672; Pub. L. 108-282, title II, § 203(a), Aug. 2, 2004, 118 Stat. 906; Pub. L. 109-462, § 3(c), Dec. 22, 2006, 120 Stat. 3475; Pub. L. 111-148, title IV, § 4205(a), (b), Mar. 23, 2010, 124 Stat. 573.)

AMENDMENTS

2010—Par. (q)(5)(A)(i). Pub. L. 111-148, § 4205(a)(1), inserted “except as provided in clause (H)(ii)(III),” before “which is served”.

Par. (q)(5)(A)(ii). Pub. L. 111-148, § 4205(a)(2), inserted “except as provided in clause (H)(ii)(III),” before “which is processed”.

Par. (q)(5)(H). Pub. L. 111-148, § 4205(b), added cl. (H). 2006—Par. (y). Pub. L. 109-462 added par. (y).

2004—Pars. (w), (x). Pub. L. 108-282 added pars. (w) and (x).

2002—Par. (h). Pub. L. 107-171, § 10808(b), added subpar. (3) and concluding provisions.

Par. (t). Pub. L. 107-171, § 10806(a)(2), added par. (t).

Par. (u). Pub. L. 107-171, § 10806(b)(2), added par. (u).

Par. (v). Pub. L. 107-188 added par. (v).

2000—Par. (o). Pub. L. 106-554, which directed repeal of section 403(o) of the Food, Drug, and Cosmetic Act, was executed by repealing par. (o) of this section, which is section 403 of the Federal Food, Drug, and Cosmetic Act, to reflect the probable intent of Congress. Prior to repeal, par. (o) provided that a food containing saccharin was to be deemed misbranded unless a specified warning statement was placed in a conspicuous place on its label.

1997—Par. (r)(2)(B). Pub. L. 105-115, § 305, amended cl. (B) generally. Prior to amendment, cl. (B) read as follows: “If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: ‘See _____ for nutrition information.’. In the statement—

“(i) the blank shall identify the panel on which the information described in the statement may be found, and

“(ii) if the Secretary determines that the food contains a nutrient at a level which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, the statement shall also identify such nutrient.”

Par. (r)(2)(G), (H). Pub. L. 105-115, § 304, added cls. (G) and (H).

Par. (r)(3)(C), (D). Pub. L. 105-115, § 303, added cls. (C) and (D).

Par. (r)(4)(A)(i). Pub. L. 105-115, § 302, inserted after second sentence “If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner.”, inserted “or the petition is deemed to be denied” after “If the Secretary denies the petition”, and inserted at end “If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rule-making shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue a regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the regulation did not occur within such 540 days.”

Par. (r)(7). Pub. L. 105-115, § 301, added subpar. (7).

1996—Par. (p). Pub. L. 104-124 struck out par. (p), which deemed products containing saccharin and offered for sale, but not for immediate consumption, by retail establishment, to be misbranded, unless notice of information required by subsec. (o) was provided by manufacturer and prominently displayed near product.

1994—Par. (q)(5)(F). Pub. L. 103-417, § 7(b), amended cl. (F) generally. Prior to amendment, cl. (F) read as follows: “If a food to which section 350 of this title applies (as defined in section 350(c) of this title) contains one or more of the nutrients required by subparagraph (1) or (2) to be in the label or labeling of the food, the label or labeling of such food shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for such food and which is specified in regulations of the Secretary.”

Par. (r)(2)(F). Pub. L. 103-417, § 7(c), added cl. (F).

Par. (r)(6). Pub. L. 103-417, § 6, added subpar. (6).

Par. (s). Pub. L. 103-417, § 10(c), inserted at end: “A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.”

Pub. L. 103-417, § 7(a), added par. (s).

1993—Par. (e). Pub. L. 103-80, § 3(j)(1), substituted “count, except that” for “count: *Provided, That*”.

Par. (i). Pub. L. 103-80, § 3(j)(2), substituted “unless sold as spices, flavorings, or such colors” for “, other