

two years from such effective date established in subsection (b)) as the Secretary of Health, Education, and Welfare [now Health and Human Services] may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period, or

“(2) on the date on which an order with respect to such use under section 409 of the Federal Food, Drug, and Cosmetic Act [section 348 of this title] becomes effective, whichever date first occurs. Whenever the Secretary has, pursuant to clause (1)(B) of this subsection, extended the effective date of section 3 of this Act [amending this section] to March 5, 1961, or has on that date a request for such extension pending before him, with respect to any such particular use of a food additive, he may, notwithstanding the parenthetical time limitation in that clause, further extend such effective date, not beyond June 30, 1964, under the authority of that clause (but subject to clause (2)) with respect to such use of the additive (or a more limited specified use or uses thereof) if, in addition to making the findings required by clause (1)(B), he finds (i) that bona fide action to determine the applicability of such section 409 [section 348 of this title] to such use or uses, or to develop the scientific data necessary for action under such section, was commenced by an interested person before March 6, 1960, and was thereafter pursued with reasonable diligence, and (ii) that in the Secretary’s judgment such extension is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary as a basis for action under such section 409 [section 348 of this title]: *Provided*, That if the Secretary has, pursuant to this sentence, granted an extension to June 30, 1964, he may, upon making the findings required by clause (1)(B) of this subsection and clauses (i) and (ii) of this sentence, further extend such effective date, but not beyond December 31, 1965. The Secretary may at any time terminate an extension so granted if he finds that it should not have been granted, or that by reason of a change in circumstances the basis for such extension no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such extension.”

EFFECTIVE DATE OF 1954 AMENDMENT

Section 5 of act July 22, 1954, provided that: “This Act [amending this section and section 321 of this title and enacting sections 346a and 346b of this title] shall take effect upon the date of its enactment [July 22, 1954], except that with respect to pesticide chemicals for which tolerances or exemptions have not been established under section 408 of the Federal Food, Drug, and Cosmetic Act [section 346a of this title], the amendment to section 402(a) of such Act [par. (a) of this section] made by section 2 of this Act shall not be effective—

“(1) for the period of one year following the date of the enactment of this Act [July 22, 1954]; or

“(2) for such additional period following such period of one year, but not extending beyond two years after the date of the enactment of this Act [July 22, 1954] as the Secretary of Health, Education, and Welfare [now Health and Human Services] may prescribe on the basis of a finding that conditions exist which necessitate the prescribing of such additional period.”

EFFECTIVE DATE OF 1950 AMENDMENT

Amendment by act Mar. 16, 1950, effective July 1, 1950, see section 7 of act Mar. 16, 1950, set out as an Effective Date note under section 347 of this title.

EFFECTIVE DATE; POSTPONEMENT

Par. (c) effective Jan. 1, 1940, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

SHORT TITLE

Pub. L. 88-625, §1, Oct. 3, 1964, 78 Stat. 1002, provided: “That this Act [amending provisions set out as a note under this section and section 135 of Title 7, Agriculture] may be cited as the ‘Food Additives Transitional Provisions Amendment of 1964’.”

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

DOMESTIC FISH OR FISH PRODUCT COMPLIANCE WITH FOOD SAFETY STANDARDS OR PROCEDURES DEEMED TO HAVE MET REQUIREMENTS FOR FEDERAL COMMODITY PURCHASE PROGRAMS

Pub. L. 104-180, title VII, §733, Aug. 6, 1996, 110 Stat. 1601, provided that: “Hereafter, notwithstanding any other provision of law, any domestic fish or fish product produced in compliance with food safety standards or procedures accepted by the Food and Drug Administration as satisfying the requirements of the ‘Procedures for the Safe and Sanitary Processing and Importing of Fish and Fish Products’ (published by the Food and Drug Administration as a final regulation in the Federal Register of December 18, 1995), shall be deemed to have met any inspection requirements of the Department of Agriculture or other Federal agency for any Federal commodity purchase program, including the program authorized under section 32 of the Act of August 24, 1935 (7 U.S.C. 612c) except that the Department of Agriculture or other Federal agency may utilize lot inspection to establish a reasonable degree of certainty that fish or fish products purchased under a Federal commodity purchase program, including the program authorized under section 32 of the Act of August 24, 1935 (7 U.S.C. 612c), meet Federal product specifications.”

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 333, 334, 346, 346a, 346b, 347b, 348, 350a, 350b, 360b, 379e of this title.

§ 343. Misbranded food

A food shall be deemed to be misbranded—

(a) False or misleading label

If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title.

(b) Offer for sale under another name

If it is offered for sale under the name of another food.

(c) Imitation of another food

If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word “imitation” and, immediately thereafter, the name of the food imitated.

(d) Misleading container

If its container is so made, formed, or filled as to be misleading.

(e) Package form

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical

count, except that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) Representation as to definition and standard of identity

If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) Representation as to standards of quality and fill of container

If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 341 of this title, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 341 of this title, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) Label where no representation as to definition and standard of identity

Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 379e(c) of this title¹ unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions

shall be established by regulations promulgated by the Secretary.

(j) Representation for special dietary use

If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) Artificial flavoring, artificial coloring, or chemical preservatives

If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

(l) Pesticide chemicals on raw agricultural commodities

If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical, except that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

(m) Color additives

If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 379e of this title.

(n) Packaging or labeling of drugs in violation of regulations

If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.

(o) Repealed. Pub. L. 106-554, §1(a)(1) [title V, §517], Dec. 21, 2000, 114 Stat. 2763, 2763A-73

(p) Repealed. Pub. L. 104-124, §1, Apr. 1, 1996, 110 Stat. 882

(q) Nutrition information

(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides—

(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or

¹ So in original. Probably should be followed by a comma.

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

(B) the number of servings or other units of measure per container,

(C) the total number of calories—

- (i) derived from any source, and
- (ii) derived from the total fat,

in each serving size or other unit of measure of the food,

(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this chapter before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

(2)(A) If the Secretary determines that a nutrient other than a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) should be included in the label or labeling of food subject to subparagraph (1) for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require that information relating to such additional nutrient be included in the label or labeling of such food.

(B) If the Secretary determines that the information relating to a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) or clause (A) of this subparagraph to be included in the label or labeling of food is not necessary to assist consumers in maintaining healthy dietary practices, the Secretary may by regulation remove information relating to such nutrient from such requirement.

(3) For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by subparagraphs (1) and (2) be displayed at the location in the retail establishment at which the food is offered for sale.

(4)(A) The Secretary shall provide for furnishing the nutrition information required by subparagraphs (1) and (2) with respect to raw agricultural commodities and raw fish by issuing voluntary nutrition guidelines, as provided by clause (B) or by issuing regulations that are mandatory as provided by clause (D).

(B)(i) Upon the expiration of 12 months after November 8, 1990, the Secretary, after providing an opportunity for comment, shall issue guidelines for food retailers offering raw agricultural commodities or raw fish to provide nutrition information specified in subparagraphs (1) and (2).

Such guidelines shall take into account the actions taken by food retailers during such 12-month period to provide to consumers nutrition information on raw agricultural commodities and raw fish. Such guidelines shall only apply—

(I) in the case of raw agricultural commodities, to the 20 varieties of vegetables most frequently consumed during a year and the 20 varieties of fruit most frequently consumed during a year, and

(II) to the 20 varieties of raw fish most frequently consumed during a year.

The vegetables, fruits, and raw fish to which such guidelines apply shall be determined by the Secretary by regulation and the Secretary may apply such guidelines regionally.

(ii) Upon the expiration of 12 months after November 8, 1990, the Secretary shall issue a final regulation defining the circumstances that constitute substantial compliance by food retailers with the guidelines issued under subclause (i). The regulation shall provide that there is not substantial compliance if a significant number of retailers have failed to comply with the guidelines. The size of the retailers and the portion of the market served by retailers in compliance with the guidelines shall be considered in determining whether the substantial-compliance standard has been met.

(C)(i) Upon the expiration of 30 months after November 8, 1990, the Secretary shall issue a report on actions taken by food retailers to provide consumers with nutrition information for raw agricultural commodities and raw fish under the guidelines issued under clause (A). Such report shall include a determination of whether there is substantial compliance with the guidelines.

(ii) If the Secretary finds that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination of the type required in subclause (i) every two years.

(D)(i) If the Secretary determines that there is not substantial compliance with the guidelines issued under clause (A), the Secretary shall at the time such determination is made issue proposed regulations requiring that any person who offers raw agricultural commodities or raw fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by subparagraphs (1) and (2). The Secretary shall issue final regulations imposing such requirements 6 months after issuing the proposed regulations. The final regulations shall become effective 6 months after the date of their promulgation.

(ii) Regulations issued under subclause (i) may require that the nutrition information required by subparagraphs (1) and (2) be provided for more than 20 varieties of vegetables, 20 varieties of fruit, and 20 varieties of fish most frequently consumed during a year if the Secretary finds that a larger number of such products are frequently consumed. Such regulations shall permit such information to be provided in a single location in each area in which raw agricultural commodities and raw fish are offered for sale. Such regulations may provide that information shall be expressed as an average or range per serving of the same type of raw agricultural

commodity or raw fish. The Secretary shall develop and make available to the persons who offer such food to consumers the information required by subparagraphs (1) and (2).

(iii) Regulations issued under subclause (i) shall permit the required information to be provided in each area of an establishment in which raw agricultural commodities and raw fish are offered for sale. The regulations shall permit food retailers to display the required information by supplying copies of the information provided by the Secretary, by making the information available in brochure, notebook or leaflet form, or by posting a sign disclosing the information. Such regulations shall also permit presentation of the required information to be supplemented by a video, live demonstration, or other media which the Secretary approves.

(E) For purposes of this subparagraph, the term "fish" includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

(F) No person who offers raw agricultural commodities or raw fish to consumers may be prosecuted for minor violations of this subparagraph if there has been substantial compliance with the requirements of this paragraph.

(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food—

(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,

(ii) which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment,

(iii) which is an infant formula subject to section 350a of this title,

(iv) which is a medical food as defined in section 360ee(b) of this title, or

(v) which is described in section 345(2) of this title.

(B) Subparagraphs (1) and (2) shall not apply to the label of a food if the Secretary determines by regulations that compliance with such subparagraphs is impracticable because the package of such food is too small to comply with the requirements of such subparagraphs and if the label of such food does not contain any nutrition information.

(C) If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subparagraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any claim with respect to the nutritional value of such food. If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.

(D) If a person offers food for sale and has annual gross sales made or business done in sales to consumers which is not more than \$500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than \$50,000, the requirements of subparagraphs (1), (2), (3), and (4) shall not apply with respect to food sold by such person to consumers unless the label or labeling of food offered by such person provides nutrition information or makes a nutrition claim.

(E)(i) During the 12-month period for which an exemption from subparagraphs (1) and (2) is claimed pursuant to this subclause, the requirements of such subparagraphs shall not apply to any food product if—

(I) the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r),

(II) the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 100 full-time equivalent employees,

(III) such person provided the notice described in subclause (iii), and

(IV) in the case of a food product which was sold in the 12-month period preceding the period for which an exemption was claimed, fewer than 100,000 units of such product were sold in the United States during such preceding period, or in the case of a food product which was not sold in the 12-month period preceding the period for which such exemption is claimed, fewer than 100,000 units of such product are reasonably anticipated to be sold in the United States during the period for which such exemption is claimed.

(ii) During the 12-month period after the applicable date referred to in this sentence, the requirements of subparagraphs (1) and (2) shall not apply to any food product which was first introduced into interstate commerce before May 8, 1994, if the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r), if such person provided the notice described in subclause (iii), and if—

(I) during the 12-month period preceding May 8, 1994, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 600,000 units of such product were sold in the United States,

(II) during the 12-month period preceding May 8, 1995, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 400,000 units of such product were sold in the United States, or

(III) during the 12-month period preceding May 8, 1996, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 200 full-time equivalent employees and fewer than 200,000 units of such product were sold in the United States.

(iii) The notice referred to in subclauses (i) and (ii) shall be given to the Secretary prior to the beginning of the period during which the ex-

emption under subclause (i) or (ii) is to be in effect, shall state that the person claiming such exemption for a food product has complied with the applicable requirements of subclause (i) or (ii), and shall—

(I) state the average number of full-time equivalent employees such person employed during the 12 months preceding the date such person claims such exemption,

(II) state the approximate number of units the person claiming the exemption sold in the United States,

(III) if the exemption is claimed for a food product which was sold in the 12-month period preceding the period for which the exemption was claimed, state the approximate number of units of such product which were sold in the United States during such preceding period, and, if the exemption is claimed for a food product which was not sold in such preceding period, state the number of units of such product which such person reasonably anticipates will be sold in the United States during the period for which the exemption was claimed, and

(IV) contain such information as the Secretary may require to verify the information required by the preceding provisions of this subclause if the Secretary has questioned the validity of such information.

If a person is not an importer, has fewer than 10 full-time equivalent employees, and sells fewer than 10,000 units of any food product in any year, such person is not required to file a notice for such product under this subclause for such year.

(iv) In the case of a person who claimed an exemption under subclause (i) or (ii), if, during the period of such exemption, the number of full-time equivalent employees of such person exceeds the number in such subclause or if the number of food products sold in the United States exceeds the number in such subclause, such exemption shall extend to the expiration of 18 months after the date the number of full-time equivalent employees or food products sold exceeded the applicable number.

(v) For any food product first introduced into interstate commerce after May 8, 2002, the Secretary may by regulation lower the employee or units of food products requirement of subclause (i) if the Secretary determines that the cost of compliance with such lower requirement will not place an undue burden on persons subject to such lower requirement.

(vi) For purposes of subclauses (i), (ii), (iii), (iv), and (v)—

(I) the term “unit” means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers,

(II) the term “food product” means food in any sized package which is manufactured by a single manufacturer or which bears the same brand name, which bears the same statement of identity, and which has similar preparation methods, and

(III) the term “person” in the case of a corporation includes all domestic and foreign affiliates of the corporation.

(F) A dietary supplement product (including a food to which section 350 of this title applies)

shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for the product and which is specified in regulations of the Secretary which shall provide that—

(i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;

(ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;

(iii) the listing of dietary ingredients may include the source of a dietary ingredient; and

(iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.

(G) Subparagraphs (1), (2), (3), and (4) shall not apply to food which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells.

(r) Nutrition levels and health-related claims

(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication—

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A)—

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary,

(ii) may not state the absence of a nutrient unless—

(I) the nutrient is usually present in the food or in a food which substitutes for the

food as defined by the Secretary by regulation, or

(II) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices and the statement discloses that the nutrient is not usually present in the food,

(iii) may not be made with respect to the level of cholesterol in the food if the food contains, as determined by the Secretary by regulation, fat or saturated fat in an amount which increases to persons in the general population the risk of disease or a health related condition which is diet related unless—

(I) the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in a food which substitutes for the food and which has a significant market share, or the Secretary by regulation permits a statement regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and the regulation requires that the statement disclose that cholesterol is not usually present in the food, and

(II) the label or labeling of the food discloses the level of such fat or saturated fat in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of cholesterol,

(iv) may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of saturated fat,

(v) may not state that a food is high in dietary fiber unless the food is low in total fat as defined by the Secretary or the label or labeling discloses the level of total fat in the food in immediate proximity to such statement and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of dietary fiber, and

(vi) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: "See nutrition information for _____ content." The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determina-

tion described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.

(C) Subparagraph (2)(A) does not apply to a claim described in subparagraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food before October 25, 1989, unless the brand name contains a term defined by the Secretary under subparagraph (2)(A)(i). Such a claim is subject to paragraph (a).

(D) Subparagraph (2) does not apply to a claim described in subparagraph (1)(A) which uses the term "diet" and is contained in the label or labeling of a soft drink if (i) such claim is contained in the brand name of such soft drink, (ii) such brand name was in use on such soft drink before October 25, 1989, and (iii) the use of the term "diet" was in conformity with section 105.66 of title 21 of the Code of Federal Regulations. Such a claim is subject to paragraph (a).

(E) Subclauses (i) through (v) of subparagraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food in relation to the amount of such vitamins and minerals recommended for daily consumption by the Secretary.

(F) Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.

(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if—

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clauses

(A) and (B), and are otherwise in compliance with paragraph (a) and section 321(n) of this title; and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(H) A claim submitted under the requirements of clause (G) may be made until—

(i) such time as the Secretary issues a regulation—

(I) prohibiting or modifying the claim and the regulation has become effective, or

(II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under subchapter III of this chapter has determined that the requirements of clause (G) have not been met.

(3)(A) Except as provided in subparagraph (5), a claim described in subparagraph (1)(B) may only be made—

(i) if the claim meets the requirements of the regulations of the Secretary promulgated under clause (B), and

(ii) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount 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, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by subparagraph (2)(B).

(B)(i) The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(ii) A regulation described in subclause (i) shall describe—

(I) the relationship between a nutrient of the type required in the label or labeling of food by paragraph (q)(1) or (q)(2) and a disease or health-related condition, and

(II) the significance of each such nutrient in affecting such disease or health-related condition.

(iii) A regulation described in subclause (i) shall require such claim to be stated in a manner so that the claim is an accurate representation of the matters set out in subclause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if—

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 321(n) of this title; and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(D) A claim submitted under the requirements of clause (C) may be made until—

(i) such time as the Secretary issues a regulation under the standard in clause (B)(i)—

(I) prohibiting or modifying the claim and the regulation has become effective, or

(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under subchapter III of this chapter has determined that the requirements of clause (C) have not been met.

(4)(A)(i) Any person may petition the Secretary to issue a regulation under subparagraph (2)(A)(i) or (3)(B) relating to a claim described in subparagraph (1)(A) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary. 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. If the Secretary denies the petition or the petition is deemed to be denied, the petition shall not be made available to the public. If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision. 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 rulemaking 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.

(ii) Any person may petition the Secretary for permission to use in a claim described in subparagraph (1)(A) terms that are consistent with the terms defined by the Secretary under subparagraph (2)(A)(i). Within 90 days of the submission of such a petition, the Secretary shall issue a final decision denying the petition or granting such permission.

(iii) Any person may petition the Secretary for permission to use an implied claim described in subparagraph (1)(A) in a brand name. After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that such claim is not misleading and is consistent with terms defined by the Secretary under subparagraph (2)(A)(i). The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be considered granted if the Secretary does not act on it within such 100 days.

(B) A petition under clause (A)(i) respecting a claim described in subparagraph (1)(A) or (1)(B)

shall include an explanation of the reasons why the claim meets the requirements of this paragraph and a summary of the scientific data which supports such reasons.

(C) If a petition for a regulation under subparagraph (3)(B) relies on a report from an authoritative scientific body of the United States, the Secretary shall consider such report and shall justify any decision rejecting the conclusions of such report.

(5)(A) This paragraph does not apply to infant formulas subject to section 350a(h) of this title and medical foods as defined in section 360ee(b) of this title.

(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 341 of this title shall not be subject to subparagraph (2)(A)(i) or (2)(B).

(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if—

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.

(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary—

(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to—

- (i) enable consumers to develop and maintain healthy dietary practices;
- (ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or
- (iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph.

Such proposed regulations shall be deemed final agency action for purposes of judicial review.

(s) Dietary supplements

If—

(1) it is a dietary supplement; and

(2)(A) the label or labeling of the supplement fails to list—

(i) the name of each ingredient of the supplement that is described in section 321(ff) of this title; and

(ii)(I) the quantity of each such ingredient; or

(II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;

(B) the label or labeling of the dietary supplement fails to identify the product by using the term “dietary supplement”, which term may be modified with the name of such an ingredient;

(C) the supplement contains an ingredient described in section 321(ff)(1)(C) of this title, and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;

(D) the supplement—

(i) is covered by the specifications of an official compendium;

(ii) is represented as conforming to the specifications of an official compendium; and

(iii) fails to so conform; or

(E) the supplement—

(i) is not covered by the specifications of an official compendium; and

(ii)(I) fails to have the identity and strength that the supplement is represented to have; or

(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.

(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.)

AMENDMENTS

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 subsec. (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 require-

ments 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 than those sold as such” and “naming each. To the extent” for “naming each: *Provided, That, to the extent*”.

Par. (k). Pub. L. 103-80, § 3(j)(3), substituted “, except that” for “: *Provided, That*”.

Par. (l). Pub. L. 103-80, § 3(j)(4), substituted “chemical, except that” for “chemical: *Provided, however, That*”.

Par. (q)(5)(E) to (G). Pub. L. 103-80, § 2(b), added cl. (E) and redesignated former cls. (E) and (F) as (F) and (G), respectively.

Par. (r)(1)(B). Pub. L. 103-80, § 3(j)(5), substituted “(5)(D)” for “(5(D))”.

Par. (r)(4)(B). Pub. L. 103-80, § 3(j)(6), substituted “paragraph” for “subsection”.

1992—Par. (i). Pub. L. 102-571, § 107(5), substituted “379e(c)” for “376(c)”.

Par. (m). Pub. L. 102-571, § 107(6), substituted “379e” for “376”.

1991—Par. (i). Pub. L. 102-108, § 2(c), amended directory language of Pub. L. 101-535, § 7(1), (3). See 1990 Amendment note below.

Par. (q)(4)(A). Pub. L. 102-108, § 2(a), substituted “(D)” for “(C)”.

1990—Par. (i). Pub. L. 101-535, § 7, as amended by Pub. L. 102-108, § 2(c), substituted “Unless” for “If it is not subject to the provisions of paragraph (g) unless”, inserted “and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food”, and substituted “colors not required to be certified under section 376(c) of this title” for “colorings” the first time appearing.

Par. (q). Pub. L. 101-535, § 2(a), added par. (q).

Par. (r). Pub. L. 101-535, § 3(a), added par. (r).

1977—Par. (o). Pub. L. 95-203, § 4(a)(1), added par. (o).

Par. (p). Pub. L. 95-203, § 4(b)(1), added par. (p).

1976—Par. (a). Pub. L. 94-278 inserted “(1)” after “If” and inserted “, or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title” after “any particular”.

1970—Par. (n). Pub. L. 91-601 added par. (n).

1960—Par. (k). Pub. L. 86-537, § 1(1), exempted pesticide chemicals when used in or on a raw agricultural commodity which is the produce of the soil.

Par. (l). Pub. L. 86-537, § 1(2), added par. (l).

Par. (m). Pub. L. 86-618 added par. (m).

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105-115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Section 7(e) of Pub. L. 103-417 provided that: “Dietary supplements—

“(1) may be labeled after the date of the enactment of this Act [Oct. 25, 1994] in accordance with the amendments made by this section [amending this section and section 350 of this title], and

“(2) shall be labeled after December 31, 1996, in accordance with such amendments.”

EFFECTIVE DATE OF 1990 AMENDMENT

Section 10(a) of Pub. L. 101-535, as amended by Pub. L. 102-571, title II, § 202(a)(3), Oct. 29, 1992, 106 Stat. 4501, provided that:

“(1) Except as provided in paragraph (2)—

“(A) the amendments made by section 2 [amending this section] shall take effect 6 months after—

“(i) the date of the promulgation of all final regulations required to implement section 403(q) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)], or

“(ii) if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations [Nov. 8, 1992, see 57 F.R. 56347],

except that section 403(q)(4) of such Act shall take effect as prescribed by such section.

“(B) the amendments made by section 3 [amending this section] shall take effect 6 months after—

“(i) the date of the promulgation of final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act, or

“(ii) if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations [Nov. 8, 1992, see 57 F.R. 56347], except that any person marketing a food the brand name of which contains a term defined by the Secretary under section 403(r)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act shall be given an

additional 6 months to comply with section 3,

“(C) the amendments made by section 4 [amending section 337 of this title] shall take effect 24 months after the date of the enactment of this Act [Nov. 8, 1990], except that such amendments shall take effect with respect to such dietary supplements [probably means dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances, see section 202(a)(1) of Pub. L. 102-571, set out below] on

December 31, 1993, and

“(D) the amendments made by section 5 [amending sections 321 and 345 of this title] shall take effect on the date the amendments made by section 3 take effect.

“(2) Section 403(q) of the Federal Food, Drug, and Cosmetic Act (as added by section 2) shall not apply with respect to food which was labeled before the effective date of the amendments made by section 2 and section 403(r) of the Federal Food, Drug, and Cosmetic Act (as added by section 3) shall not apply with respect to food which was labeled before the effective date of the amendments made by section 3.

“(3)(A) If the Secretary finds that a person who is subject to section 403(q)(4) of such Act is unable to comply with the requirements of such section upon the effective date of final regulations to implement section 403(q) of such Act or of proposed regulations to be considered as such final regulations because the Secretary has not made available to such person the information required by such section, the Secretary shall delay the application of such section to such person for such time as the Secretary may require to provide such information.

“(B) If the Secretary finds that compliance with section 403(q) or 403(r)(2) of such Act would cause an undue economic hardship, the Secretary may delay the application of such sections for no more than one year.”

Section 10(c) of Pub. L. 101-535, as amended by Pub. L. 102-108, § 1, Aug. 17, 1991, 105 Stat. 549; Pub. L. 102-571, title I, § 107(17), Oct. 29, 1992, 106 Stat. 4500, provided that:

“(1) Except as provided in paragraphs (2) and (3), the amendments made by section 7 [amending this section] shall take effect one year after the date of the enactment of this Act [Nov. 8, 1990].

“(2)(A) If a food subject to section 403(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(g)] or a food with one or more colors required to be certified under section 721(c) [of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 379e(c)] bears a label which was printed before July 1, 1991, and which is attached to the food before May 8, 1993, such food shall not be subject to the amendments made by section 7(1) and section 7(3) [amending this section].

“(B) If a food described in subparagraph (A)—

“(i) bears a label which was printed after July 1, 1991, but before the date the proposed regulation described in clause (ii) takes effect as a final regulation and which was attached to the food before May 8, 1993, and

“(ii) meets the requirements of the proposed regulation of the Secretary of Health and Human Services published in 56 Fed. Reg. 28592-28636 (June 21, 1991) as it pertains to the amendments made by this Act [see Short Title of 1990 Amendment note set out under section 301 of this title],

such food shall not be subject to the amendments made by section 7(1) and section 7(3) [amending this section].

“(3) A food purported to be a beverage containing a vegetable or fruit juice which bears a label attached to the food before May 8, 1993, shall not be subject to the amendments made by section 7(2) [amending this section].”

EFFECTIVE DATE OF 1977 AMENDMENT

Section 4(a)(2) of Pub. L. 95-203 provided that: “The amendment made by paragraph (1) [amending this section] shall apply only with respect to food introduced or delivered for introduction in interstate commerce on and after the 90th day after the date of the enactment of this Act [Nov. 23, 1977].”

Section 4(b)(2) of Pub. L. 95-203 provided that: “The amendment made by paragraph (1) [amending this section] shall apply with respect to food which is sold in retail establishments on or after the 90th day after the effective date of the regulations of the Secretary of Health, Education, and Welfare [now Secretary of Health and Human Services] under paragraph (p)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(p)(4)].”

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94-278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94-278, set out as a note under section 334 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91-601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 8 of Pub. L. 91-601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86-618, see section 202 of Pub. L. 86-618, set out as a note under section 379e of this title.

EFFECTIVE DATE; POSTPONEMENT

Subsecs. (e)(1) and (g) to (k) effective Jan. 1, 1940, and such subsections effective July 1, 1940, as provided by regulations for certain lithographed labeling and containers bearing certain labeling, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Section 9 of Pub. L. 101-535 provided that: “The amendments made by this Act [enacting section 343-1

of this title and amending this section and sections 321, 337, 345, and 371 of this title] shall not be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], the Federal Meat Inspection Act [21 U.S.C. 601 et seq.], the Poultry Products Inspection Act [21 U.S.C. 451 et seq.], and the Egg Products Inspection Act [21 U.S.C. 1031 et seq.]”

REGULATIONS

Section 2(b) of Pub. L. 101-535, as amended by Pub. L. 102-571, title II, § 202(a)(2)(A), (B), Oct. 29, 1992, 106 Stat. 4500, 4501, provided that:

“(1) The Secretary of Health and Human Services shall issue proposed regulations to implement section 403(q) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)] within 12 months after the date of the enactment of this Act [Nov. 8, 1990], except that the Secretary shall issue, not later than June 15, 1993, proposed regulations that are applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances to implement such section. Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement the requirements of such section, except that the Secretary shall issue, not later than December 31, 1993, such a final regulation applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances. [sic] Such regulations shall—

“(A) require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet,

“(B) include regulations which establish standards, in accordance with paragraph (1)(A), to define serving size or other unit of measure for food,

“(C) permit the label or labeling of food to include nutrition information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section, and

“(D) permit the nutrition information on the label or labeling of a food to remain the same or permit the information to be stated as a range even though (i) there are minor variations in the nutritional value of the food which occur in the normal course of the production or processing of the food, or (ii) the food is comprised of an assortment of similar foods which have variations in nutritional value.

“(2) If the Secretary of Health and Human Services does not promulgate final regulations under paragraph (1) upon the expiration of 24 months after the date of the enactment of this Act, the proposed regulations issued in accordance with paragraph (1) shall be considered as the final regulations upon the expiration of such 24 months, except that the proposed regulations applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances shall not be considered to be final regulations until December 31, 1993. There shall be promptly published in the Federal Register notice of new status of the proposed regulations [see 57 F.R. 56347].

“(3) If the Secretary of Health and Human Services does not promulgate final regulations under section 403(q)(4) of the Federal Food, Drug, and Cosmetic Act upon the expiration of 6 months after the date on which the Secretary makes a finding that there has been no substantial compliance with section 403(q)(4)(C) of such Act, the proposed regulations issued in accordance with such section shall be considered as the final regulations upon the expiration of such 6 months. There shall be promptly published in the Federal Register notice of new status of the proposed regulations.”

[Section 202(a)(2)(C) of Pub. L. 102-571 provided that: “The amendments made by subparagraph (B) [amending sections 2(b) and 3(b) of Pub. L. 101-535, set out above and below] shall not be construed to modify the effective date of final regulations under sections 2(b)

and 3(b) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101-535] (21 U.S.C. 343 note) with respect to foods that are not such dietary supplements.”]

Section 3(b) of Pub. L. 101-535, as amended by Pub. L. 102-571, title II, §202(a)(2)(A), (B), Oct. 29, 1992, 106 Stat. 4500, 4501, provided that:

“(1)(A) Within 12 months of the date of the enactment of this Act [Nov. 8, 1990], the Secretary of Health and Human Services shall issue proposed regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(r)], except that the Secretary shall issue, not later than June 15, 1993, proposed regulations that are applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances to implement such section. Such regulations—

“(i) shall identify claims described in section 403(r)(1)(A) of such Act which comply with section 403(r)(2) of such Act,

“(ii) shall identify claims described in section 403(r)(1)(B) of such Act which comply with section 403(r)(3) of such Act,

“(iii) shall, in defining terms used to characterize the level of any nutrient in food under section 403(r)(2)(A)(i) of such Act, define—

- “(I) free,
- “(II) low,
- “(III) light or lite,
- “(IV) reduced,
- “(V) less, and
- “(VI) high,

unless the Secretary finds that the use of any such term would be misleading,

“(iv) shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act,

“(v) shall provide that if multiple claims subject to section 403(r)(1)(A) of such Act are made on a single panel of the food label or page of a labeling brochure, a single statement may be made to satisfy section 403(r)(2)(B) of such Act,

“(vi) shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(3) of such Act: Calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease,

“(vii) shall not require a person who proposes to make a claim described in section 403(r)(1)(B) of such Act which is in compliance with such regulations to secure the approval of the Secretary before making such claim,

“(viii) may permit a claim described in section 403(r)(1)(A) of such Act to be made for butter,

“(ix) may, in defining terms under section 403(r)(2)(A)(i), include similar terms which are commonly understood to have the same meaning, and

“(x) shall establish, as required by section 403(r)(5)(D), the procedure and standard respecting the validity of claims made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances and shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(5)(D) of such Act: folic acid and neural tube defects, antioxidant [sic] vitamins and cancer, zinc and immune function in the elderly, and omega-3 fatty acids and heart disease.

“(B) Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act, except that the Secretary shall issue, not later than December 31, 1993, such a final regulation applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances..[sic]

“(2) If the Secretary does not promulgate final regulations under paragraph (1)(B) upon the expiration of 24

months after the date of the enactment of this Act, the proposed regulations issued in accordance with paragraph (1)(A) shall be considered as the final regulations upon the expiration of such 24 months, except that the proposed regulations applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances shall not be considered to be final regulations until December 31, 1993. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations [see 57 F.R. 56347].”

[For construction of amendment made by section 202(a)(2)(B) of Pub. L. 102-571 to section 3(b) of Pub. L. 101-535 set out above, see section 202(a)(2)(C) of Pub. L. 102-571 set out above following section 2(b) of Pub. L. 101-535.]

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

COMMISSION ON DIETARY SUPPLEMENT LABELS

Section 12 of Pub. L. 103-417 provided that:

“(a) ESTABLISHMENT.—There shall be established as an independent agency within the executive branch a commission to be known as the Commission on Dietary Supplement Labels (hereafter in this section referred to as the ‘Commission’).

“(b) MEMBERSHIP.—

“(1) COMPOSITION.—The Commission shall be composed of 7 members who shall be appointed by the President.

“(2) EXPERTISE REQUIREMENT.—The members of the Commission shall consist of individuals with expertise and experience in dietary supplements and in the manufacture, regulation, distribution, and use of such supplements. At least three of the members of the Commission shall be qualified by scientific training and experience to evaluate the benefits to health of the use of dietary supplements and one of such three members shall have experience in pharmacognosy, medical botany, traditional herbal medicine, or other related sciences. Members and staff of the Commission shall be without bias on the issue of dietary supplements.

“(c) FUNCTIONS OF THE COMMISSION.—The Commission shall conduct a study on, and provide recommendations for, the regulation of label claims and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims. In making such recommendations, the Commission shall evaluate how best to provide truthful, scientifically valid, and not misleading information to consumers so that such consumers may make informed and appropriate health care choices for themselves and their families.

“(d) ADMINISTRATIVE POWERS OF THE COMMISSION.—

“(1) HEARINGS.—The Commission may hold hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable to carry out the purposes of this section.

“(2) INFORMATION FROM FEDERAL AGENCIES.—The Commission may secure directly from any Federal department or agency such information as the Commission considers necessary to carry out the provisions of this section.

“(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

“(e) REPORTS AND RECOMMENDATIONS.—

“(1) FINAL REPORT REQUIRED.—Not later than 24 months after the date of enactment of this Act [Oct. 25, 1994], the Commission shall prepare and submit to

the President and to the Congress a final report on the study required by this section.

“(2) RECOMMENDATIONS.—The report described in paragraph (1) shall contain such recommendations, including recommendations for legislation, as the Commission deems appropriate.

“(3) ACTION ON RECOMMENDATIONS.—Within 90 days of the issuance of the report under paragraph (1), the Secretary of Health and Human Services shall publish in the Federal Register a notice of any recommendation of Commission for changes in regulations of the Secretary for the regulation of dietary supplements and shall include in such notice a notice of proposed rulemaking on such changes together with an opportunity to present views on such changes. Such rulemaking shall be completed not later than 2 years after the date of the issuance of such report. If such rulemaking is not completed on or before the expiration of such 2 years, regulations of the Secretary published in 59 FR 395-426 on January 4, 1994, shall not be in effect.”

EXTENSION OF COMPLIANCE DEADLINE FOR CERTAIN FOOD PRODUCTS PACKAGED PRIOR TO AUGUST 8, 1994

Pub. L. 103-261, May 26, 1994, 108 Stat. 705, provided: “That before August 8, 1994, sections 403(q) and 403(r)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q), (r)(2)] and the provision of section 403(i) of such Act added by section 7(2) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101-535], shall not apply with respect to a food product which is contained in a package for which the label was printed before May 8, 1994 (or before August 8, 1994, in the case of a juice or milk food product if the person responsible for the labeling of such food product exercised due diligence in obtaining before such date labels which are in compliance with such sections 403(q) and 403(r)(2) and such provision of section 403(i)), if, before June 15, 1994, the person who introduces or delivers for introduction such food product into interstate commerce submits to the Secretary of Health and Human Services a certification that such person will comply with this section and will comply with such sections 403(q) and 403(r)(2) and such provision of section 403(i) after August 8, 1994.”

LIMITATIONS ON APPLICATION OF SMALL BUSINESS EXEMPTION

Section 2(a) of Pub. L. 103-80 provided that:

“(1) BEFORE MAY 8, 1995.—Before May 8, 1995, the exemption provided by section 403(q)(5)(D) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(q)(5)(D)] shall be available in accordance with the regulations of the Secretary of Health and Human Services published at 21 C.F.R. 101.9(j)(1)(i)(1993).

“(2) AFTER MAY 8, 1995.—After May 8, 1995, the exemption provided by section 403(q)(5)(D) of the Federal Food, Drug, and Cosmetic Act shall only be available with respect to food when it is sold to consumers.”

PROHIBITION ON IMPLEMENTATION OF PUB. L. 101-535 WITH RESPECT TO DIETARY SUPPLEMENTS

Section 202(a)(1) of Pub. L. 102-571 provided that: “Notwithstanding any other provision of law and except as provided in subsection (b) [set out as a note below] and in the amendment made by paragraph (2)(A) [amending provisions set out as notes above], the Secretary of Health and Human Services may not implement the Nutrition Labeling and Education Act of 1990 (Public Law 101-535; 104 Stat. 2353) [see Short Title of 1990 Amendments note set out under section 301 of this title], or any amendment made by such Act, earlier than December 15, 1993, with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances.”

HEALTH CLAIMS MADE WITH RESPECT TO DIETARY SUPPLEMENTS

Section 202(b) of Pub. L. 102-571 provided that: “Notwithstanding section 403(r)(5)(D) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 343(r)(5)(D)) and subsection (a) [enacting provisions set out as notes above and amending provisions set out as notes above and under section 343-1 of this title], the Secretary of Health and Human Services may, earlier than December 15, 1993, approve claims made with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances that are claims described in clauses (vi) and (x) of section 3(b)(1)(A) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101-535] (21 U.S.C. 343 note).”

UNITED STATES RECOMMENDED DAILY ALLOWANCES OF VITAMINS OR MINERALS

Section 203 of Pub. L. 102-571 provided that: “Notwithstanding any other provision of Federal law, no regulations that require the use of, or are based upon, recommended daily allowances of vitamins or minerals may be promulgated before November 8, 1993 (other than regulations establishing the United States recommended daily allowances specified at section 101.9(c)(7)(iv) of title 21, Code of Federal Regulations, as in effect on October 6, 1992, or regulations under section 403(r)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(1)(A)) that are based on such recommended daily allowances).”

CONSUMER EDUCATION

Section 2(c) of Pub. L. 101-535 provided that: “The Secretary of Health and Human Services shall carry out activities which educate consumers about—

“(1) the availability of nutrition information in the label or labeling of food, and

“(2) the importance of that information in maintaining healthy dietary practices.”

STUDIES CONCERNING CARCINOGENIC AND OTHER TOXIC SUBSTANCES IN FOOD AND IMPURITIES IN AND TOXICITY OF SACCHARIN

Section 2 of Pub. L. 95-203 directed Secretary of Health, Education, and Welfare to conduct a study concerning carcinogenic and other toxic substances in food and impurities in and toxicity of saccharin and make a report respecting the carcinogenic and other substances to Committee on Human Resources of the Senate within 12 months of Nov. 23, 1977, and a report respecting saccharin to such committee within 15 months of Nov. 23, 1977.

REPORT TO CONGRESSIONAL COMMITTEES RESPECTING ACTION TAKEN PURSUANT TO FORMER PAR. (o)(2)

Section 4(a)(3) of Pub. L. 95-203 provided that the Secretary was to report to specified congressional committees any action taken under former par. (o)(2) of this section.

STATE OR TERRITORIAL REQUIREMENTS

Section 2 of Pub. L. 86-537 provided that: “Nothing in the amendments made by the first section of this Act [amending this section] shall affect any requirement of the laws of any State or Territory.”

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 333, 334, 337, 343-1, 343-3, 345, 347, 350, 371 of this title.

§ 343-1. National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section