

§ 4.32

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required by § 4.32, even though such information is not set forth in the manner and form as required by § 4.32 and other sections of this title referred to therein, and (2) bear no statements, designs, or devices which are false or misleading.

(b) *Alteration of labels.* (1) It shall be unlawful for any person to alter, mutilate, destroy, obliterate or remove any mark, brand, or label upon wine held for sale in interstate or foreign commerce or after shipment therein, except as authorized by Federal law, or except as provided in paragraph (b)(2) of this section: *Provided*, That the appropriate TTB officer may, upon written application, permit additional labeling or relabeling of wine for purposes of compliance with the requirements of this part or of State law.

(2) No application for permission to relabel wine need be made in any case where there is added to the container, after removal from customs custody or from the premises where bottled or packed, a label identifying the wholesale or retail distributor thereof, and containing no reference whatever to the characteristics of the product.

[T.D. 6521, 25 FR 13835, Dec. 29, 1960, as amended by T.D. ATF-425, 65 FR 11891, Mar. 7, 2000; T.D. ATF-953, 68 FR 39455, July 2, 2003]

CROSS REFERENCE: For customs warehouses and control of merchandise therein, see 19 CFR part 19.

§ 4.32 Mandatory label information.

(a) There shall be stated on the brand label:

(1) Brand name, in accordance with § 4.33.

(2) Class, type, or other designation, in accordance with § 4.34.

(3) Alcohol content, in accordance with § 4.36.

(4) On blends consisting of American and foreign wines, if any reference is made to the presence of foreign wine, the exact percentage by volume.

(b) There shall be stated on any label affixed to the container:

(1) Name and address, in accordance with § 4.35.

(2) Net contents, in accordance with § 4.37. If the net contents is a standard of fill other than an authorized metric standard of fill as prescribed in § 4.73,

the net contents statement shall appear on a label affixed to the front of the bottle.

(c) There shall be stated on the brand label or on a back label a statement that the product contains FD&C Yellow No. 5, where that coloring material is used in a product bottled on or after October 6, 1984.

(d) [Reserved]

(e) *Declaration of sulfites.* There shall be stated on a front label, back label, strip label or neck label, the statement “Contains sulfites” or “Contains (a) sulfiting agent(s)” or a statement identifying the specific sulfiting agent where sulfur dioxide or a sulfiting agent is detected at a level of 10 or more parts per million, measured as total sulfur dioxide. The provisions of this paragraph shall apply to:

(1) Any certificate of label approval issued on or after January 9, 1987;

(2) Any wine bottled on or after July 9, 1987, regardless of the date of issuance of the certificate of label approval; and,

(3) Any wine removed on or after January 9, 1988.

(Paragraph (e) approved by the Office of Management and Budget under Control Number 1512-0469)

[T.D. 6521, 25 FR 13835, Dec. 29, 1960, as amended by T.D. ATF-150, 48 FR 45556, Oct. 6, 1983; T.D. ATF-195, 50 FR 763, Jan. 7, 1985; T.D. ATF-220, 50 FR 51852, Dec. 20, 1985; T.D. ATF-236, 51 FR 34710, Sept. 30, 1986; T.D. ATF-282, 54 FR 7162, Feb. 16, 1989; T.D. ATF-312, 56 FR 31076, 31077, July 9, 1991; T.D. TTB-12, 69 FR 33573, June 16, 2004]

§ 4.32a Voluntary disclosure of major food allergens.

(a) *Definitions.* For purposes of this section the following terms have the meanings indicated.

(1) *Major food allergen.* *Major food allergen* means any of the following:

(i) Milk, egg, fish (for example, bass, flounder, or cod), Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts (for example, almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

(ii) A food ingredient that contains protein derived from a food specified in paragraph (a)(1)(i) of this section, except:

(A) Any highly refined oil derived from a food specified in paragraph

(a)(1)(i) of this section and any ingredient derived from such highly refined oil; or

(B) A food ingredient that is exempt from major food allergen labeling requirements pursuant to a petition for exemption approved by the Food and Drug Administration (FDA) under 21 U.S.C. 343(w)(6) or pursuant to a notice submitted to FDA under 21 U.S.C. 343(w)(7), provided that the food ingredient meets the terms or conditions, if any, specified for that exemption.

(2) *Name of the food source from which each major food allergen is derived.* Name of the food source from which each major food allergen is derived means the name of the food as listed in paragraph (a)(1)(i) of this section, except that:

(i) In the case of a tree nut, it means the name of the specific type of nut (for example, almonds, pecans, or walnuts);

(ii) In the case of Crustacean shellfish, it means the name of the species of Crustacean shellfish (for example, crab, lobster, or shrimp); and

(iii) The names “egg” and “peanuts”, as well as the names of the different types of tree nuts, may be expressed in either the singular or plural form, and the term “soy”, “soybean”, or “soya” may be used instead of “soybeans”.

(b) *Voluntary labeling standards.* Major food allergens (defined in paragraph (a)(1) of this section) used in the production of a wine may, on a voluntary basis, be declared on any label affixed to the container. However, if any one major food allergen is voluntarily declared, all major food allergens used in production of the wine, including major food allergens used as fining or processing agents, must be declared, except when covered by a petition for exemption approved by the appropriate TTB officer under § 4.32b. The major food allergens declaration must consist of the word “Contains” followed by a colon and the name of the food source from which each major food allergen is derived (for example, “Contains: egg”).

(c) *Cross reference.* For mandatory labeling requirements applicable to wines containing FD&C Yellow No. 5 and sulfites, see §§ 4.32(c) and (e).

[T.D. TTB-53, 71 FR 42267, July 26, 2006]

§ 4.32b Petitions for exemption from major food allergen labeling.

(a) *Submission of petition.* Any person may petition the appropriate TTB officer to exempt a particular product or class of products from the labeling requirements of § 4.32a. The burden is on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the finished product or class of products, as derived by the method specified in the petition, either:

(1) Does not cause an allergic response that poses a risk to human health; or

(2) Does not contain allergenic protein derived from one of the foods identified in § 4.32a(a)(1)(i), even though a major food allergen was used in production.

(b) *Decision on petition.* TTB will approve or deny a petition for exemption submitted under paragraph (a) of this section in writing within 180 days of receipt of the petition. If TTB does not provide a written response to the petitioner within that 180-day period, the petition will be deemed denied, unless an extension of time for decision is mutually agreed upon by the appropriate TTB officer and the petitioner. TTB may confer with the Food and Drug Administration (FDA) on petitions for exemption, as appropriate and as FDA resources permit. TTB may require the submission of product samples and other additional information in support of a petition; however, unless required by TTB, the submission of samples or additional information by the petitioner after submission of the petition will be treated as the withdrawal of the initial petition and the submission of a new petition. An approval or denial under this section will constitute a final agency action.

(c) *Resubmission of a petition.* After a petition for exemption is denied under this section, the petitioner may resubmit the petition along with supporting materials for reconsideration at any time. TTB will treat this submission as a new petition for purposes of the time frames for decision set forth in paragraph (b) of this section.