

§7.22a

Drug Administration (FDA) regulations:

“PHENYLKETONURICS: CONTAINS PHENYLALANINE.”

(Paragraph (b)(6) approved by the Office of Management and Budget under Control No. 1512-0469)

[T.D. 6521, 25 FR 13859, Dec. 29, 1960]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §7.22, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§7.22a 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); and

(ii) In the case of Crustacean shellfish, it means the name of the species

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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 name “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 malt beverage product 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 malt beverage product, 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 §7.22b. 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 malt beverage products containing FD&C Yellow No. 5, sulfites, and aspartame, see §§7.22(b)(4), (b)(6), and (b)(7).

[T.D. TTB-53, 71 FR 42269, July 26, 2006]

§7.22b 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 §7.22a. 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 §7.22(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.

(d) *Availability of information—(1) General.* TTB will promptly post to its public Web site, <http://www.ttb.gov>, all petitions received under this section as well as TTB's responses to those petitions. Any information submitted in support of the petition that is not posted to the TTB Web site will be available to the public pursuant to 5 U.S.C. 552, except where a request for confidential treatment is granted under paragraph (d)(2) of this section.

(2) *Requests for confidential treatment of business information.* A person who provides trade secrets or other commercial or financial information in connection with a petition for exemption under this section may request that TTB give confidential treatment to that information. A failure to request confidential treatment at the time the information in question is submitted to TTB will constitute a waiver of confidential treatment. A request for confidential treatment of information under this section must conform to the following standards:

(i) The request must be in writing;

(ii) The request must clearly identify the information to be kept confidential;

(iii) The request must relate to information that constitutes trade secrets or other confidential commercial or financial information regarding the business transactions of an interested person, the disclosure of which would cause substantial harm to the competitive position of that person;

(iv) The request must set forth the reasons why the information should not be disclosed, including the reasons the disclosure of the information would prejudice the competitive position of the interested person; and

(v) The request must be supported by a signed statement by the interested person, or by an authorized officer or employee of that person, certifying that the information in question is a trade secret or other confidential commercial or financial information and that the information is not already in the public domain.

[T.D. TTB-53, 71 FR 42269, July 26, 2006]

§ 7.23 Brand names.

(a) *General.* The product shall bear a brand name, except that if not sold under a brand name, then the name of the person required to appear on the brand label shall be deemed a brand name for the purpose of this part.

(b) *Misleading brand names.* No label shall contain any brand name, which, standing alone, or in association with other printed or graphic matter, creates any impression or inference as to the age, origin, identity, or other characteristics of the product unless the appropriate TTB officer finds that such brand name, either when qualified by the word "brand" or when not so qualified, conveys no erroneous impressions as to the age, origin, identity, or other characteristics of the product.

(c) *Trade name of foreign origin.* This section shall not operate to prohibit the use by any person of any trade name or brand of foreign origin not effectively registered in the United States Patent Office on August 29, 1935, which has been used by such person or his predecessors in the United States for a period of at least 5 years immediately preceding August 29, 1935: *Provided*, That if such trade name or brand