

§ 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