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FDA Releases Guidance for Food Allergen Labeling Exemptions

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The ***Food and Drug Administration*** (FDA) issued final guidance for industry on June 19 titled "Food Allergen Labeling Exemption Petitions and Notifications." This guidance was preceded by draft guidance by the same name. The FDA received comments on the draft guidance and considered them when making revisions to the final guidance. The final guidance explains the FDA's thinking on the submission of petitions and notifications for obtaining exemptions from labeling requirements for major food allergens under the ***Food, Drug, and Cosmetic Act*** (FD&C Act).

In 2004, the Food Allergen Labeling and Consumer Protect Act (FALCPA) created a new food misbranding charge regarding the labeling of major food allergens. FALCPA amended the FD&C Act to state that foods that failed to declare the presence of a major food allergen on the product label would be considered misbranded. The FD&C Act defines a major food allergen as "milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans." Section 321(qq) also defines a major food allergen as a food ingredient that contains protein derived from the listed foods. However, FALCPA provided two pathways for certain ingredients derived from major food allergens to be exempt from allergen labeling requirements. Section 403 allows a person to petition the Secretary of the Department of Health and Human Services to exempt a major food allergen ingredient. Section 403 also states that a person need not file a petition if he or she files a notification with the Secretary.

Certain ingredients derived from major food allergens are modified to such an extent that they lack the offending allergenic protein. Additionally, it is possible for a

major food allergen to be used as an ingredient such that the level of the allergenic protein in the finished food product does not cause an allergic response. The two FALCPA exemption pathways allow these types of ingredients to avoid major food allergen labeling requirements. Both pathways require a showing that the ingredient "does not cause an allergic response that poses a risk to human health." First, an ingredient may become exempt through a petition process under which a petitioner has the burden of proof to present scientific evidence, including (in some cases) clinical studies of oral food challenges or skin prick testing to prove that the ingredient will not provoke an allergic response that poses a risk to human health. Second, an ingredient may become exempt through submission of a notification that contains scientific evidence that the ingredient "does not contain allergenic protein" or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act.

Both types of submissions will require an ingredient description, the method or procedure used to prepare or manufacture the ingredient, an ingredient protein characterization, a description of the intended use in the final food product, and methods used to obtain the scientific evidence. Petitions should contain information on the expected consumer exposure during a single consumption of the finished food product and clinical studies or risk modeling, using data on consumer exposure. Notifications should contain protein characterization, with a preference for clinical data, and any relevant animal or *in vitro* studies. The FDA will evaluate the scientific evidence for the specific ingredient and for the specific use of the ingredient as stated in the submission. According to the FDA, the submitter should determine whether a petition or notification is most appropriate for the ingredient and its specific uses. Finally, the FD&C Act requires all petitions and notifications as well as the FDA's response to be posted publicly. The inventory of petitions received since 2004 can be found here, and the inventory of notifications can be found here. To date, eight notifications and three petitions have been filed. One petition has been approved (soy), and one notification has been approved (fish). The final guidance will provide direction to entities interested in having an ingredient exempted from major food allergen labeling requirements.