



U.S. FDA Publishes New Food Allergen Labeling Questions and Answers Guidance Document

The U.S. Food and Drug Administration (FDA) recently issued two food allergen labeling documents. The first document is a draft guidance document, *Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)*. Some highlights from the new draft guidance include:

- Adding sesame as a major food allergen effective January 1, 2023
- Explanations on what types of foods, food ingredients, and foods sources apply to the food allergen labeling requirements
 - Including information and examples on how to label spice and seasoning mixes
 - A list of “fish” species the FDA considers allergenic including: Jawless fish, such as hagfish and lampreys; Bony fish, such as trout, flounder, bass, salmon, tilapia, cod, mackerel, tuna, and grouper; Cartilaginous fish, such as shark, rays, and skates
 - An explanation that food and food ingredients that contain proteins derived from the major food allergens apply to the food allergen labeling requirements. Including, proteins from major food allergens produced in other sources through the use of genetic engineering.
 - For example: “A protein derived from cow milk, but produced via fermentation in a non-milk food source, such as a genetically engineered strain of yeast... Such food ingredients should be declared in a way that makes the relationship to the source allergen clear. Some examples of how that could be achieved are: ‘Contains milk-derived protein’ or ‘[ingredient name] (milk-derived protein)’.”
 - A table with examples of tree nuts with the common or usual and scientific names
- Information on what products, foods, and food ingredients do not apply to the food allergen labeling requirements
 - Pet food, OTC drugs, cosmetics, and household cleaning products do not apply to the food allergen labeling requirements
 - “Roots, leaves, stems, bark, or other parts that are distinct from the tree nut portion of the plant are not major food allergens”
- Specific food allergen labeling examples such as,
 - How a multiunit or multicomponent food should be labeled
 - How to declare allergens when a single ingredient contains multiple allergens and how to declare an allergen when present in multiple ingredients
 - How to declare food allergens that are not one of the nine major food allergens
 - Dietary supplement allergen labeling

The second document is a “final guidance with the same title to preserve the questions and answers from the previous edition (Edition 4) that were not changed, except for editorial changes such as renumbering the questions and reorganizing the information in the guidance.”

Constituent Update: <https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-guidances-food-allergen-labeling-requirements>

How Does this Impact You? Contact Us to Discuss

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