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October xx, 2006

Guidance for Industry

Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004

(Edition 4)*

Final Guidance

Comments and suggestions regarding this document may be submitted at any time. Submit comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
October 5, 2006**

Guidance for Industry

Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling

2005D-0490

GDL 2

and Consumer Protection Act of 2004 (Edition 4)

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I. Introduction

As originally enacted in 1938, section 403(i) of the Federal Food, Drug, and Cosmetic Act required that the label of a food that is fabricated from two or more ingredients declare each ingredient by its common or usual name (except that spices, flavorings, and colors could be declared as a class.) Although ingredient declarations complying with section 403(i) provide some information to food allergic consumers, in some cases, the common or usual name of an ingredient may be unfamiliar to consumers and many consumers do not recognize that certain ingredients contain or are derived from a food allergen. This situation led, at least in part, to the enactment of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Pub. L. 108-282).

This is a revision of the third edition of a guidance document that contains questions and answers relating to food allergens, including questions and answers about the Food Allergen Labeling and Consumer Protection Act. FDA expects to continue to issue subsequent editions of this guidance document by adding new questions and answers to the guidance; new questions and answers will be identified by the date that they are added to the guidance.

FDA's guidance documents, including this document, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Questions and Answers

1. What is the Food Allergen Labeling and Consumer Protection Act of 2004?

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Public Law 108-282) was enacted in August 2004, and addresses, among other issues, the labeling of foods that contain certain food allergens.

2. When do the labeling requirements of the Food Allergen Labeling and Consumer Protection Act (FALCPA) become effective for packaged foods sold in the United States?

All packaged foods regulated under the Federal Food, Drug, and Cosmetic Act (FFD&C Act) that are labeled on or after January 1, 2006, must comply with FALCPA's food allergen labeling

requirements.

3. Must products with labels that do not comply with FALCPA be removed from the market place once the new labeling law is effective?

No. FALCPA does not require any action with respect to products labeled before January 1, 2006.

4. What is a "major food allergen?"

Under FALCPA, a "major food allergen" is an ingredient that is one of the following five foods or from one of the following three food groups or is an ingredient that contains protein derived from one of the following:

- milk
- egg
- fish
- Crustacean shellfish
- tree nuts
- wheat
- peanuts
- soybeans

5. Does FALCPA provide any specific direction for declaring the presence of ingredients from the three food groups that are designated as "major food allergens (i.e., tree nuts, fish, and Crustacean shellfish?")

Yes. FALCPA requires that in the case of tree nuts, the specific type of nut must be declared (e.g., almonds, pecans, or walnuts). The species must be declared for fish (e.g., bass, flounder, or cod) and Crustacean shellfish (crab, lobster, or shrimp).

6. Are there food allergens other than those directly addressed by FALCPA?

Congress designated eight foods or food groups as "major food allergens." These foods or food groups account for 90 percent of all food allergies. Although there are other foods to which sensitive individuals may react, the labels of packaged foods containing these other allergens are not required to be in compliance with FALCPA.

7. What types of foods are covered by the FALCPA labeling requirements?

FALCPA's requirements apply to all packaged foods sold in the U.S. that are regulated under the Federal Food, Drug, & Cosmetic Act, including both domestically manufactured and imported foods. FDA regulates all foods except meat products, poultry products, and egg products.

8. Are fresh fruits and vegetables in their natural state subject to FALCPA's requirements?

No. Raw agricultural commodities such as fresh fruits and vegetables in their natural state are not affected by FALCPA.

9. Does FALCPA affect the labeling of packaged meat, poultry, and egg products regulated by the U.S. Department of Agriculture (USDA)?

FALCPA's requirements apply only to those foods regulated by the Food and Drug Administration under the FFD&C Act. We recommend that producers of meat products, poultry products, and egg products regulated by USDA contact the appropriate USDA agency regarding the labeling of such products.

10. **May the terms "soybean," "soy," and "soya" be considered synonyms for the term "soybeans" for the purpose of satisfying the FALCPA labeling requirements?**

Yes. "Soybean," "soy," and "soya" are reasonable synonyms for the common or usual name "soybeans," and any one of these terms may be used to identify the food source of the major food allergen "soybeans."

11. **When is it appropriate to use the term "soybeans" versus a synonym in food labeling?**

Packaged foods that are made using soybeans as an ingredient or as a component of a multi-component ingredient (e.g., soy sauce or tofu) should continue to use the word "soybeans" as the appropriate common or usual name for this ingredient to identify properly the ingredient (e.g., "soy sauce (water, wheat, soybeans, salt)").

12. **May the singular term "peanut" be substituted for the plural term "peanuts," and may the singular terms (e.g., almond, pecan, or walnut) be used to describe the different types of "tree nuts" (e.g., almonds, pecans, or walnuts) to satisfy the labeling requirements of FALCPA?**

Yes. FDA believes that "peanut" is an acceptable substitute for "peanuts" and that the names of the different types of tree nuts may be expressed in either the singular or plural form for the purpose of satisfying the FALCPA labeling requirements.

13. **May a "Contains" statement on a food label provided in accordance with FALCPA list only the names of the food sources of the major food allergens that are not already identified in the ingredient list for a packaged food?**

No. If a "Contains" statement is used on a food label, the statement must include the names of the food sources of all major food allergens used as ingredients in the packaged food. For example, if "sodium caseinate," "whey," "egg yolks," and "natural peanut flavor" are declared in a product's ingredients list, any "Contains" statement appearing on the label immediately after or adjacent to that statement is required to identify all three sources of the major food allergens present (e.g., "Contains milk, egg, peanuts") in the same type (i.e., print or font) size as that used for the ingredient list.

14. **Is there more than one way to word a "Contains" statement used to declare the major food allergens in a packaged food?**

Yes. The wording for a "Contains" statement may be limited to just stating the word "Contains" followed by the names of the food sources of all major food allergens that either are or are contained in ingredients used to make the packaged product. Alternatively, additional wording may be used for a "Contains" statement to more accurately describe the presence of any major food allergens, provided that the following three conditions are met:

- a. The word "Contains" with a capital "C" must be the first word used to begin a "Contains" statement. (The use of bolded text and punctuation within a "Contains" statement is

optional.)

- b. The names of the food sources of the major food allergens declared on the food label must be the same as those specified in the FALCPA, except that the names of food sources may be expressed using singular terms versus plural terms (e.g., walnut versus walnuts) and the synonyms "soy" and "soya" may be substituted for the food source name "soybeans."
- c. If included on a food label, the "Contains" statement must identify the names of the food sources for all major food allergens that either are in the food or are contained in ingredients of the food.

15. Is there a penalty for non-compliance with FALCPA?

Yes. A company and its management may be subject to civil sanctions, criminal penalties, or both under the Federal Food, Drug, and Cosmetic Act if one of its packaged food products does not comply with the FALCPA labeling requirements. FDA may also request seizure of food products where the label of the product does not conform to FALCPA's requirements. In addition, FDA is likely to request that a food product containing an undeclared allergen be recalled by the manufacturer or distributor.

16. Does FALCPA require food manufacturers to label their products with advisory statements, such as "may contain [allergen]" or "processed in a facility that also processes [allergen]?"

No. FALCPA does not address the use of advisory labeling, including statements describing the potential presence of unintentional ingredients in food products resulting from the food manufacturing process. FALCPA does require FDA to submit a report to Congress, a part of which assesses the use of, and consumer preferences about, advisory labeling. In earlier guidance, FDA advised that advisory labeling such as "may contain [allergen]" should not be used as a substitute for adherence to current Good Manufacturing Practices (cGMPs). In addition, any advisory statement such as "may contain [allergen]" must be truthful and not misleading.

17. Does FALCPA require FDA to set so-called thresholds for any food allergen?

FALCPA does not require FDA to establish a threshold level for any food allergen. It is not unlikely, however, that FDA will at some point need to consider a threshold level for one or more food allergens in the context of reviewing a petition or a notification submitted to request that an ingredient be exempt from FALCPA's labeling requirements.

18. [Added December, 2005] Is a major food allergen that has been unintentionally added to a food as the result of cross-contact subject to FALCPA's labeling requirements?

No. FALCPA's labeling requirements do not apply to major food allergens that are unintentionally added to a food as the result of cross-contact. In the context of food allergens, "cross-contact" occurs when a residue or other trace amount of an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food. Cross-contact may result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment.

19. [Added April, 2006] What information has been added to the 2005 FDA Food Code related to food allergens?

FDA's Food Code is a model code available for adoption by local, state, and other jurisdictions to apply to all food establishments at the retail level that provide food directly to consumers, including: restaurants, grocery stores, supermarkets, hospitals, nursing homes, child care centers, and temporary food establishments.

The following new food allergen information has been added to the 2005 Food Code:

- A definition of "major food allergen," which is consistent with the definition in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) [Paragraph 1-201.10(B)].
- A new provision under Demonstration of Knowledge [Subparagraph 2-102.11(C)(9)] specifying that the person in charge of a food establishment shall have an understanding of the foods identified as major food allergens and the symptoms that a major food allergen could cause in a sensitive individual. This additional element is significant because nationally recognized certifiers of food managers who provide training and testing of such managers consult these elements when the certifiers routinely upgrade their training and testing programs.
- Integration of FALCPA's labeling provisions to reflect the additional requirements that apply to food that is packaged at the retail level [Subparagraph 3-602.11(B)(5)].
- Additional background information on food allergens in Annex 4, including common characteristics of a food allergic response and detailed information regarding the requirements of FALCPA.

20. [Added April, 2006] Do retail and foodservice establishments have to comply with FALCPA's labeling requirements?

FALCPA's labeling requirements extend to foods packaged by a retail or foodservice establishment that are offered for human consumption. However, FALCPA's labeling requirements do not apply to foods provided by a retail food establishment that are placed in a wrapper or container in response to a consumer's order - such as the paper or box used to convey a sandwich that has been prepared in response to a consumer's order.

21. [Added April, 2006] Do the FALCPA requirements apply regardless of whether a jurisdiction has adopted the 2005 FDA Food Code?

Yes. Although the 2005 FDA Food Code contains provisions to integrate FALCPA's requirements into the model code as well as additional food allergen information in its Annexes, FALCPA is a federal law that amends the Federal Food, Drug, & Cosmetic Act (FFDCA). Thus, regardless of whether a jurisdiction has adopted the 2005 Food Code, FALCPA's requirements apply to all packaged foods in interstate commerce, both domestically manufactured and imported, sold in the U.S. that are regulated under the FFDCA. FDA regulates all foods except meat products, poultry products, and certain egg products. FALCPA is specifically preemptive, which means that other governmental entities (such as those at the state or local level) may not adopt labeling requirements that are different from those in FALCPA.

22. [Added April, 2006] Does FALCPA address the use of advisory labeling (such as "may contain") by a retail or food service establishment?

No. FALCPA does not address the use of advisory labeling, including statements describing the potential presence of unintentional ingredients in food products resulting from the manufacturing

of the ingredients or the preparation and packaging of the food in a retail or food service establishment. All food labeling, including advisory labeling, must be truthful and not misleading. See FDA's 1996 Notice to Manufacturers.

23. [Added April, 2006] Are molluscan shellfish considered a major food allergen under FALCPA?

No. Under FALCPA, Crustacean shellfish (such as crab, lobster, or shrimp), and ingredients that contain protein derived from Crustacean shellfish, are major food allergens, but molluscan shellfish (such as oysters, clams, mussels, or scallops) are not.

24. [Added April, 2006] Does FDA intend to issue additional guidance for retail and foodservice establishments on the proper handling of food allergens?

As stipulated in FALCPA, FDA is engaged in an on-going effort to work with the Conference for Food Protection on the development of guidelines for retail and foodservice establishments on the proper handling and labeling of food allergens.

25. [Added October, 2006] Section 201(qq) of the Act defines the term "major food allergen" to include "tree nuts." In addition to the three examples provided in section 201(qq) (almonds, pecans, and walnuts), what nuts are considered "tree nuts?"

The following are considered "tree nuts" for purposes of section 201(qq). The name listed as "common or usual name" should be used to declare the specific type of nut as required by section 403(w)(2).

Common or usual name	Scientific name
Almond	<i>Prunus dulcis</i> (Rosaceae)
Beech nut	<i>Fagus</i> spp. (Fagaceae)
Brazil nut	<i>Bertholletia excelsa</i> (Lecythidaceae)
Butternut	<i>Juglans cinerea</i> (Juglandaceae)
Cashew	<i>Anacardium occidentale</i> (Anacardiaceae)
Chestnut (Chinese, American, European, Seguin)	<i>Castanea</i> spp. (Fagaceae)
Chinquapin	<i>Castanea pumila</i> (Fagaceae)
Coconut	<i>Cocos nucifera</i> L. (Arecaceae (alt. Palmae))
Filbert/hazelnut	<i>Corylus</i> spp. (Betulaceae)
Ginko nut	<i>Ginkgo biloba</i> L. (Ginkgoaceae)

Hickory nut	<i>Carya</i> spp. (Juglandaceae)
Lichee nut	<i>Litchi chinensis</i> Sonn. Sapindaceae
Macadamia nut/Bush nut	<i>Macadamia</i> spp. (Proteaceae)
Pecan	<i>Carya illinoensis</i> (Juglandaceae)
Pine nut/Pinon nut	<i>Pinus</i> spp. (Pineaceae)
Pili nut	<i>Canarium ovatum</i> Engl. in A. DC. (Burseraceae)
Pistachio	<i>Pistacia vera</i> L. (Anacardiaceae)
Sheanut	<i>Vitellaria paradoxa</i> C.F. Gaertn. (Sapotaceae)
Walnut (English, Persian, Black, Japanese, California), Heartnut, Butternut	<i>Juglans</i> spp. (Juglandaceae)

The foregoing list reflects FDA's current best judgment as to those nuts that are "tree nuts" within the meaning of section 201(qq). In order to be comprehensive, this list employs broad scientific categories that may include a species that currently has no food use. The fact that a species falls within a scientific category on this list does not mean that the species is appropriate for food use. FDA further advises that, as with any guidance, the list may be revised consistent with the process for revising guidance documents in our regulation on good guidance practices in 21 CFR 10.115.

26. [Added October, 2006] Under section 403(w)(1), a major food allergen must be declared using the name of the food source from which the major food allergen is derived. Section 403(w)(2) provides that, in the case of fish or Crustacean shellfish, the term "name of the food source from which the major food allergen is derived" means the "species" of fish or Crustacean shellfish. What is the "species" of fish or Crustacean shellfish for purposes of section 403(w)(2)?

A declaration of the "species" of fish or Crustacean shellfish for purposes of complying with section 403(w)(2) should be made using the acceptable market name provided in FDA's Seafood List. FDA's Seafood List is a compilation of existing acceptable market names for imported and domestically available seafood. The list is available at <http://www.cfsan.fda.gov/~frf/seaintro.html>.

27. [Added October, 2006] Section 201(qq) includes "wheat" in the definition of major food allergen. What is considered "wheat" for purposes of section 201(qq)?

The term "wheat" in section 201(qq) means any species in the genus *Triticum*. Thus, for the purposes of section 201(qq), wheat would include grains such as common wheat (*Triticum aestivum* L.), durum wheat (*Triticum durum* Desf.), club wheat (*Triticum compactum* Host.), spelt (*Triticum spelta* L.), semolina (*Triticum durum* Desf.), Einkorn (*Triticum monococcum* L. subsp. *monococcum*), emmer (*Triticum turgidum* L. subsp. *dicoccon* (Schrank) Thell.), kamut (*Triticum polonicum* L.), and triticale (x *Triticosecale* ssp. Wittm.).

28. [Added October, 2006] Are single ingredient foods required to comply with section 403(w)(1)?

Yes. Single ingredient foods must comply with the allergen declaration requirements in section 403(w)(1). A single ingredient food that is, or contains protein derived from milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, or soybeans, may identify the food source in the name of the food (e.g., "all-purpose wheat flour") or use the "Contains" statement format. FDA recommends that if a "Contains" statement format is used, the statement be placed immediately above the manufacturer, packer, or distributor statement. For single ingredient foods intended for further manufacturing where the "Contains" statement format is used, the statement should be placed on the principal display panel of the food.

* This is a revision of the third edition of the FDA guidance "Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004," which FDA issued on April 6, 2006.

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