Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry

Additional copies are available from:
Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
240-402-1450
https://www.fda.gov/FoodGuidances

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2022-D-0099.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

November 2022

Table of Contents

Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

As originally enacted in 1938, section 403(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that the label of a food that is fabricated from two or more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 noncertified colors can be declared as such) (21 U.S.C. 343(i)). However, consumers may be unfamiliar with the common or usual name of an ingredient and may not recognize that certain ingredients contain or are derived from a food allergen. The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Public Law 108-282) was enacted in August 2004, and, in part, amended the FD&C Act by defining the term "major food allergen" (21 U.S.C. 321(qq)) and stating that foods regulated under the FD&C Act are misbranded unless they declare the presence of each major food allergen on the product label using the name of the food source from which the major food allergen is derived. Section 403(w)(1) of the FD&C Act sets forth the requirements for declaring the presence of each major food allergen on the product label. In addition, the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act) (Public Law 117-11) was enacted in April 2021 and, in part, amended the

[1] This guidance has been prepared by the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

definition of major food allergens in section 201(qq) of the FD&C Act to include sesame, effective January 1, 2023.

This is a revision of the fourth edition of a guidance document originally entitled "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004." This revision contains questions and answers from the fourth edition that constitute final guidance, but with editorial changes, such as renumbering and organization. FDA expects to continue to issue subsequent editions of this guidance document by revising existing questions and answers and by adding new questions and answers.

This final guidance document accompanies the 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)*. In this pair of guidance documents, FDA is issuing the new or revised questions and answers in the draft guidance document, will receive comments on the draft questions and answers, and, as appropriate, will move the questions and answers to this final guidance document, after reviewing comments and incorporating suggested changes to the question and answer, when appropriate. Note that a question and answer that is in the final guidance document may be withdrawn and moved to a new or revised draft guidance document if FDA determines that the question and answer should be revised and reissued in draft for comment. A question and answer also may be withdrawn and removed from the guidance documents if, for instance, the issue addressed in the question and answer is addressed elsewhere. For ease of reference, a question and answer retains the same number when it moves from the draft guidance document to the final guidance document and we use the term "RESERVED" after each numbered question and answer, where appropriate, to facilitate this process.

For more information related to allergens, please see http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/default.htm.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances 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 FDA guidances means that something is suggested or recommended, but not required.

II. Questions and Answers

A. General Information

A.1 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

A.2 Are there foods or food groups that are allergens, other than those designated as "major food allergens" under the FD&C Act?

Yes. FALCPA stated that the eight foods or food groups designated by FALCPA account for 90 percent of all food allergies in the United States at the time of its passage, but there are over 160 foods that have been reported to cause allergic reactions. Although sensitive individuals may react to other foods, the labels of packaged foods containing allergens from foods other than the major food allergens are not required to list the food source of those allergens in the way required by the FD&C Act.

A.3 Do the food allergen labeling requirements of the FD&C Act require FDA to set so-called "thresholds" for any food allergen?

No, the food allergen labeling requirements of the FD&C Act do not require FDA to establish a threshold level for any food allergen. See https://www.fda.gov/food/food-labeling-nutrition/approaches-establish-thresholds-major-food-allergens-and-gluten-food.

A.4 As a manufacturer, is it possible to request that my food ingredient be exempt from food allergen labeling requirements of the FD&C Act?

Yes. Under section 403(w)(6) and (7) of the FD&C Act, any person can ask FDA for a labeling exemption for an ingredient derived from a major food allergen when it does not cause an allergic response that poses a risk to human health or when it does not contain allergenic protein. A request for an exemption from food allergen labeling can be made either through a petition process or a notification process. See http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm395494.htm

The petition process requires scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the food ingredient described in the petition does not cause an allergic response that poses a risk to human health. The notification process must include scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the food ingredient described in the notification does not contain an allergenic protein or is the subject of a premarket approval or notification program under section 409 of the FD&C Act. If FDA grants the petition or does not object to the notification, then the ingredient is not considered a major food allergen and is not subject to the food allergen labeling requirements of the FD&C Act.

For a list of petition and notification requests, see Inventory of Petitions Received under 21 U.S.C. 343(w)(6) for Exemptions from Food Allergen Labeling and Inventory of Notifications Received under 21 U.S.C. 343(w)(7) for Exemptions from Food Allergen Labeling.

A.5 Is there a penalty for failure to comply with the food allergen labeling requirements under section 403(w) of the FD&C Act?

Yes. FDA can carry out a number of regulatory actions if a food label fails to comply with the

food allergen labeling requirements under the FD&C Act. Such products are misbranded and subject to enforcement actions such as recalls, import refusal, and seizure by FDA. Food facilities making such food may be issued warning letters or put on FDA's import alerts. When there is a problem that justifies a recall, firms generally recall such food products from the marketplace voluntarily.

B. Types of Foods That Fall Under the Food Allergen Labeling Requirements of the FD&C Act

B.1 What types of foods do the food allergen labeling requirements of the FD&C Act apply to?

All packaged foods, including dietary supplements, in the United States or its territories and subject to FDA regulations, that are domestically manufactured or imported into the United States, are covered by the allergen labeling requirements of the FD&C Act (except most meat, poultry, catfish, and certain processed egg products[2]). (See section on dietary supplements below.)

B.2 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

B.3 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

B.4 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

B.5 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

B.6 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

---

[2] Most meat (Federal Meat Inspection Act Public law 91-201, 21 U.S.C. 601-624), poultry (Poultry Products Inspection Act Public Law 90-492, 21 U.S.C. 451-471), catfish (Federal Meat Inspection Act Public law 91-201, 21 U.S.C. 601-624), and certain processed egg products (Egg Products Inspection Act Public Law 91-597, 21 U.S.C. 1031-1056) are regulated by the U.S. Department of Agriculture. Please see USDA's website for information about labeling of allergens in these foods.

B.7 Are molluscan shellfish considered a major food allergen under the FD&C Act?

No. Under section 201(qq) of the FD&C Act, 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.

B.8 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

B.9 Are raw agricultural commodities, such as fresh fruits and vegetables in their natural state, subject to the food allergen labeling requirements of the FD&C Act?

No. Raw agricultural commodities, such as fresh fruits and vegetables in their natural state, are not subject to the food allergen labeling requirements of the FD&C Act.

B.10 Are packaged meat, poultry, catfish, and processed egg products regulated by the U.S. Department of Agriculture (USDA) and alcohol products regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB) subject to the food allergen labeling requirements of the FD&C Act?

No. The food allergen labeling requirements of the FD&C Act apply only to those foods regulated by FDA under the FD&C Act. We recommend that producers of meat, poultry, catfish, processed egg, and alcohol products regulated by USDA and TTB contact the appropriate agency regarding the labeling of such products.[3]

B.11 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

B.12 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

---

[3] For information regarding jurisdiction of alcoholic beverages please see the FDA's beer labeling guidance https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-labeling-certain-beers-subject-labeling-jurisdiction-food-and-drug-administration and the 1974 Memorandum of Understanding Between The Bureau of Alcohol, Tobacco and Firearms and The Food and Drug Administration regarding the Promulgation and Enforcement of the Labeling Regulations Promulgated under the Federal Alcohol Administration Act: https://www.fda.gov/about-fda/domestic-mous/distilled-spirits

B.13 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

B.14 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

C. Food Sources

The questions in this section give additional information on the terms that must be used to declare major food allergens on the label. The FD&C Act requires that the name of the food source from which the major food allergen is derived be declared on the label as follows:

- Milk
- Egg
- The specific species of fish (e.g., bass, flounder, tilapia, salmon or cod)
- The specific species of Crustacean shellfish (e.g., crab, lobster, or shrimp)
- The specific type of tree nut (e.g., almond, pecans, or walnuts)
- Wheat
- Peanuts
- Soybeans
- Sesame (effective date January 1, 2023)

C.1 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

C.2 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

C.3 Do the food allergen labeling requirements of the FD&C Act 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. Section 403(w) of the FD&C Act requires that the specific type of tree nut be declared (e.g., almonds, pecans, or walnuts). It also requires that the species must be declared for fish (e.g., bass, flounder, or cod) and Crustacean shellfish (e.g., crab, lobster, or shrimp) (section 403(w)(2) of the FD&C Act). This means the ingredient list or the "Contains" statement cannot broadly declare "tree nuts," "fish," or "Crustacean shellfish" as the major food allergen.

C.4 For the purposes of the food allergen labeling requirements of the FD&C Act, what is the "species" of fish or Crustacean shellfish?

For the ingredient list, manufacturers should declare the acceptable market name or the common name provided in FDA's Seafood List as the "species" of fish or Crustacean shellfish. Both names may alternatively be used as the statement of identity. However, for the "Contains" statement, in addition to one of these names being used, manufacturers may use the generic name, e.g., Salmon for Chum Salmon or Flounder for Peacock or Tropical Flounder. FDA's Seafood List of acceptable market names for imported and domestically available seafood is available at https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=SeafoodList

C.5 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

C.6 For the purposes of complying with the food allergen labeling requirements of the FD&C Act, what is "wheat"?

Wheat is a "major food allergen" under the FD&C Act. For purposes of the definition of a "major food allergen," the term "wheat" means any species in the genus *Triticum*. Thus, 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.).

C.7 Is it acceptable to use a singular term to satisfy the food allergen labeling requirements if the FD&C Act identifies a major food allergen using a plural term?

Yes. FDA considers it acceptable to use a singular term even if the FD&C Act identifies the major food allergen using a plural term. For example, it is acceptable to use "peanut" rather than "peanuts" or "almond, pecan, or walnut" rather than "almonds, pecans, or walnuts," respectively.

C.8 Are there synonyms for the common or usual name "soybeans" for the purpose of satisfying the food allergen labeling requirements of the FD&C Act in some circumstances?

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" as appropriate.

D. The Food Allergen Labeling Requirements of the FD&C Act

D.1 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

D.2 Are single ingredient foods required to comply with the food allergen labeling requirements of the FD&C Act?

Yes. Single ingredient foods must comply with the food allergen labeling requirements in section 403(w)(1) of the FD&C Act. 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 Statement of Identity, i.e., name of the food (e.g., "All-purpose wheat flour"), or use the "Contains" statement format. Because a single-ingredient food does not require an ingredient list, FDA recommends that if a "Contains" statement format is used for a retail package, 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, we recommend that the Contains statement be placed on the front of the package of the food near the statement of identity. See Figure 5 below.

Figure 1. Example of a single ingredient food intended for further manufacturing where the "Contains" statement is on the front of the food package.

D.3 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

D.4 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

D.5 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

D.6 May a "Contains" statement on a food label provide 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 is to include the names of the food sources of all major food allergens used as ingredients in the packaged food (see section 403(w)(1) of the FD&C Act). For example, if sodium caseinate, whey, egg yolks, and natural peanut flavor are declared in a product's ingredients list, a "Contains" statement appearing on the label immediately after or adjacent to that statement is to identify all three food 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.

D.7 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 (see section 403(w) of the FD&C Act). 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 (see section 403(w) of the FD&C Act):

1. The word "Contains" with a capital "C" is the first word used to begin a "Contains" statement. (The use of bolded text and punctuation within a "Contains" statement is optional.)
2. The names of the food sources of the major food allergens declared on the food label are the same as those specified in section 403(w) of the FD&C Act, 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 soybeans.
3. If included on a food label, the "Contains" statement is to 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.

D.8 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

D.9 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

D.10 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

D.11 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

D.12 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

D.13 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

D.14 Does section 403(w) of the FD&C Act address the use of allergen advisory labeling (such as "may contain")?

No. Section 403(w) of the FD&C Act does not address the use of allergen advisory labeling, including statements describing the potential presence of unintentional allergens 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. Advisory labeling, such as "may contain [allergen]," is not a substitute for adherence to current good manufacturing practices and, when used by a facility, food allergen preventive controls. In addition, any advisory statement such as "may contain [allergen]" must be truthful and not misleading.

D.15 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

D.16 Do retail and foodservice establishments have to comply with the food allergen labeling requirements of the FD&C Act?

The food allergen labeling requirements of the FD&C Act extend to foods packaged by a retail or foodservice establishment that are offered for human consumption. However, these labeling requirements do not apply to foods provided by a retail or food service establishment that are placed in a wrapper or container in response to a consumer's order, such as the paper or box used to transport a sandwich that has been prepared in response to a consumer's order.

D.17 What is the Food Code and how does it pertain to food allergens?

FDA's Food Code is a model code available for local, state, and other jurisdictions to adopt and apply to retail food establishments, including restaurants, grocery stores, supermarkets, hospitals, nursing homes, child-care centers, and temporary food establishments that provide food directly to consumers. The 2017 FDA Food Code contains provisions regarding food allergens in the model code as well as food allergen information in its annexes. The 2017 Food Code specifies the following information pertaining to food allergens:

- A definition of "major food allergen," which is consistent with the definition in section 201(qq) of the FD&C Act (Paragraph 1-201.10(B)).
- Under Knowledge - Demonstration, 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 (Subparagraph 2-102.11(C)(9)). This element is significant because nationally recognized certifiers train and test food managers and consult these elements when routinely upgrading training and testing programs.
- Under Duties - Person in Charge, the person in charge shall ensure that employees of the food establishment are properly trained in food safety, including food allergy awareness, as it relates to their assigned duties (Subparagraph 2.103.11(M)). This allows industry to develop and implement operational-specific training programs for food employees.
- Under Labeling - Food Labels, label information for food that is packaged at the retail level includes the food allergen labeling provisions of the FD&C Act (Subparagraph 3-602.11(B)(5)).
- Under Frequency - Equipment Food-Contact Surfaces and Utensils, cleaning and sanitizing frequency for food contact surfaces or utensils that are in contact with a raw animal food that is a major food allergen such as fish, followed by other types of raw animal foods are specified (Subparagraph 4-602.11).
- Additional background information on food allergens in Annex 4, including common characteristics of a food allergic response and detailed information regarding the food allergen labeling requirements of the FD&C Act.

D.18 Do the food allergen labeling requirements of the FD&C Act apply regardless of whether a jurisdiction has adopted the 2017 FDA Food Code?

Yes. FALCPA and the FASTER Act are federal laws that amended the FD&C Act. Thus, regardless of whether a jurisdiction has adopted the 2017 Food Code, the requirements of these laws apply to domestically manufactured or imported packaged foods regulated under the FD&C Act (see question B.1). FDA regulates all packaged foods except most meat, poultry, catfish, and certain processed egg products. These laws also preempt State and local laws, which means that other governmental entities (such as those at the state or local level) may not adopt labeling requirements that are not identical to those in section 403(w) of the FD&C Act.

E. Dietary Supplements

E.1 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

E.2 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

E.3 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

E.4 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

E.5 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

E.6 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

E.7 RESERVED – See the draft guidance "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)."

III. Paperwork Reduction Act of 1995

This guidance document refers to previously approved collections of information found in federal laws. The collections of information in section 403(w) of the FD&C Act have been approved under OMB control no. 0910-0792.