Contains Nonbinding Recommendations

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

You can comment on any guidance at any time (see 21 CFR 10.115(g)(5)). 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.

For questions regarding this document, contact the Human Foods Program at HFP-Policy@fda.hhs.gov.

Additional copies are available at https://www.fda.gov/FoodGuidances.

U.S. Department of Health and Human Services
Food and Drug Administration
Human Foods Program

January 2025

OMB Control No. 0910-0792
Current expiration date available at https://www.reginfo.gov/public/do/PRAMain
See additional PRA statement in Section III of this guidance.

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]

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As originally enacted in 1938, section 403(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that the label of a food that is fabricated from two or more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 certain 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" (section 201(qq) of the FD&C Act (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 definition of major food allergen in section 201(qq) of the FD&C Act to include sesame.

This is a revision of the fifth edition of this guidance document that adds the questions and answers from the draft guidance document, *Questions and Answers Regarding Food Allergens,*

[1] This guidance has been prepared by the Office of Nutrition and Food Labeling, Human Foods Program at the U.S. Food and Drug Administration.

Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5), that are now being finalized. Editorial changes, such as renumbering and organizational changes have also been made in this revision. 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.

For more information related to food 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 FDA'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 What foods and food groups are designated as "major food allergens"?

Under section 201(qq) of the FD&C Act, a "major food allergen" is one of the following foods or food groups, or an ingredient that contains protein derived from one of the following:

Foods	**Food Groups**
Milk	Fish (such as bass, flounder, cod)
Eggs	Crustacean shellfish (such as crab, lobster, shrimp)
Peanuts	Tree nuts (such as almonds, walnuts, pecans)
Wheat	
Soybeans	
Sesame	

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. There are over 160 foods that have been reported to cause allergic reactions in addition to the list of major food allergens that account for most food allergies in the United States. 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 Can FDA change the list of major food allergens that are defined in the FD&C Act?

As explained above in section I. Introduction, the FD&C Act defines "major food allergen." FDA cannot alter the statutory list of the nine major food allergens, but the law also allows FDA to require labeling for food allergens other than those designated as major food allergens when

appropriate. For example, a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen) as determined by the Secretary by regulation, must be disclosed in a manner specified by the Secretary by regulation under section 403(x) of the FD&C Act.

A.4 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. FDA has previously examined the topic of thresholds but has not established specific thresholds for any food allergens. See https://www.fda.gov/food/food-labeling-nutrition/approaches-establish-thresholds-major-food-allergens-and-gluten-food.

A.5 As a manufacturer, can I 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 the petition or notification process. See https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-allergen-labeling-exemption-petitions-and-notifications.

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 (21 U.S.C. 348). 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 petitions and notifications received, 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.6 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 proceed with various 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 Federal Food, Drug, and Cosmetic 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 Are food ingredients and finished foods subject to the food allergen labeling requirements of the FD&C Act?

Yes. Food ingredients and finished foods (including those used to make dietary supplements, such as liquids, solids, powders, capsules, soft gels, and tablets) that contain a major food allergen must comply with the allergen labeling requirements of section 403(w) of the FD&C Act. This is the case whether they are packaged in bulk or retail containers. Food manufacturers need to know whether any major food allergens are present in the food ingredients they use to manufacture other products to ensure that ingredients containing major food allergens are properly handled and that finished product labels comply with the FD&C Act.

B.3 Do the food allergen labeling requirements of the FD&C Act apply to bulk containers, such as reusable totes or containers of bulk food shipped for further processing, labeling, or repacking between manufacturers, repackers, or distributors such as tanker trucks? Can foods subject to these requirements be exempted through the use of a written agreement under 21 CFR 101.100(d)(2)?

The food allergen labeling requirements of the FD&C Act apply to bulk containers such as reusable totes or containers of bulk food shipped for further processing, labeling, or repacking between manufacturers, repackers, or distributors (see Figure 1). We do not consider tanker vehicles (e.g., tanker trucks or tanker trains) to be "packages" that must be labeled.

While a food shipment may be exempt from most of the mandatory food labeling requirements through the use of a written agreement in accordance with 21 CFR 101.100(d), these regulations do not provide an exemption for food allergen labeling requirements. Consistent with section 403(f) and (w) of the FD&C Act, major food allergen declarations must be prominently placed on the container with such conspicuousness so as to render it likely to be read.

---

[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. See USDA's website for information about labeling of allergens in these foods.

Figure 1. Example of a reusable container of milk that declares the name of the food source from which the major food allergen is derived in a "Contains" statement. The ingredient in this figure is either being shipped between two firms that are under the same ownership (21 CFR 101.100(d)(1)) or between two firms that have a written agreement (21 CFR 101.100(d)(2)), so is exempt from most other mandatory labeling.

B.4 In my food manufacturing facilities, I purchase spice mixes and seasoning mixes in bulk that contain a major food allergen as a free flow agent.

(a) How do I declare spice mixes in the ingredient list of my finished product? How do I declare an incidental additive that is a major food allergen in the spice mix?

In general, foods that are made from two or more ingredients must declare the common or usual name of each ingredient except those ingredients exempted by 21 CFR 101.100, like incidental additives (21 CFR 101.4(a)(1)). However, spices may be declared simply as "spices" on the finished product label (21 CFR 101.4(b)(1) and 101.22(h) and section 403(i)(2) of the FD&C Act). If a major food allergen is present in a spice mix ingredient and the major food allergen is an incidental additive in the finished food, you still must declare it on the label of the finished food (section 403(w) of the FD&C Act). Specifically, you could declare it parenthetically after the term "spice(s)" in the ingredient list, or in a separate "Contains" statement, or both. See

Figure 2 below for an example.

Figure 2. Example of snack bags declaring the major food allergen "wheat" in the ingredient list or in the "Contains" statement. In this situation, wheat flour is used as an anticaking agent in the "spices" ingredient, and it is an incidental additive in the finished chips products. In the image to the left, wheat is declared in the ingredients. In the image to the right, because wheat is not declared in the ingredient list, it must be declared in a "Contains" statement (section 403(w)(4) of the FD&C Act).

(b) How do I declare seasoning mixes in the ingredient list of my finished product?

A seasoning mix may contain ingredients that are not spices, e.g., salt. If you add a seasoning mix ingredient to your product, you must declare the sub-ingredients of the seasoning mix by their common or usual names in the ingredient list of your finished food (see 21 CFR 101.4(b)(2)). Additionally, if a major food allergen is present in the seasoning mix ingredient and the major food allergen is an incidental additive in the finished food, you still must declare it on the label of the finished food (section 403(w) of the FD&C Act). If major food allergens are present in the seasoning mix and the common or usual names declared do not include the source of the major food allergen, then you must declare the presence of all major food allergens in the ingredient list, the "Contains" statement, or both (section 403(w) of the FD&C Act). See Figure 3.

Figure 3. Example of snack bags declaring the major food allergen "milk" in the ingredient list or in the "Contains" statement. In the image to the left, "milk" is declared in parentheses after "whey" in the ingredient list. In the image to the right, "milk" is declared in a "Contains" statement.

B.5 How should sesame be declared if it is part of a spice mix used in my finished food?

Sub-ingredients of a spice mix used in a finished food may be declared using the collective term "spice" or "spices" such that the common or usual name of the spice ingredient does not appear in the ingredient list. If, however, such a sub-ingredient is a major food allergen that is not declared elsewhere in the ingredient list, to meet the food allergen labeling requirements, it must be declared in a "Contains" statement (section 403(w) of the FD&C Act). For example, "sesame" must be declared in a "Contains" statement or in a parenthetical after the collective term "spice" or "spices" in the ingredient list, i.e., "Contains sesame" or "spices (sesame)."

B.6 Are ingredients, including dietary supplement ingredients, derived from other parts of the same plant that bears tree nuts or other food sources of major food allergens subject to the food allergen labeling requirements of the FD&C Act?

It depends. The food allergen labeling requirements under the FD&C Act are applicable if a food is or contains proteins from a major food allergen (sections 403(w) and 201(qq) of the FD&C Act). Ingredients derived from a plant that bears a major food allergen but do not contain proteins from that major food allergen are not subject to FDA's allergen labeling requirements described in section 403(w)(1) of the FD&C Act.

Therefore, if the ingredient does not contain protein from a major food allergen, then you are not required to declare the major food allergen on the label. If, however, the ingredient is obtained or processed in such a way that it contains residual protein from the major food allergen, then the ingredient would be subject to the food allergen labeling requirements.

The manufacturer may consider the Food Allergen Labeling Exemption Petitions and Notifications guidance if they believe that their ingredient qualifies for a labeling exemption from section 403(w)(1) of the FD&C Act.

B.7 Lactose is a milk sugar and ghee is a milk-derived fat. As a manufacturer, do I have to declare milk on the label if I use these ingredients?

The FD&C Act requires allergen labeling of a food or ingredient that is or contains protein from a major food allergen (sections 403(w) and 201(qq) of the FD&C Act). Ingredients derived from a major food allergen that do not contain proteins are not subject to FDA's allergen labeling requirements. If your major food allergen-derived ingredient is processed using technology that reliably produces a protein-free ingredient and you can demonstrate that the ingredient does not contain protein, then you do not have to declare the major food allergen on the label. Because lactose is a milk sugar and ghee is a milk-derived fat, residual protein from milk is often present in these ingredients. When that is the case, lactose and ghee must be labeled in accordance with section 403(w)(1) of the FD&C Act. However, the manufacturer may consider Food Allergen Labeling Exemption Petitions and Notifications if the firm believes that their ingredient qualifies for an exemption from section 403(w) of the FD&C Act.

B.8 When is a food ingredient derived from a major food allergen not subject to the food allergen labeling requirements of the FD&C Act?

Besides highly refined oils, which are specifically exempt from the definition of "major food allergen," food ingredients (including flavors, colors, and incidental additives) derived from a major food allergen are not subject to the food allergen labeling requirements of the FD&C Act when the food ingredients do not contain a protein derived from the major food allergen (section 201(qq)(2) of the FD&C Act). Ingredients that contain protein derived from a major food allergen may also become exempt from the labeling requirements of section 403(w)(1) of the FD&C Act through FDA's Food Allergen Labeling Exemption Petitions and Notifications processes.

B.9 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.10 Which species of "fish" does FDA consider allergenic?

For purposes of section 201(qq) of the FD&C Act, FDA interprets "fish" as consisting of three categories:

- 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

B.11 Are raw agricultural commodities, such as fresh fruits and vegetables and certain seafood products in their natural state, subject to the food allergen labeling requirements of the FD&C Act?

No. Raw agricultural commodities,[3] such as fresh fruits and vegetables and certain seafood products in their natural state, are not subject to the food allergen labeling requirements of the FD&C Act.

B.12 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.[4]

---

[3] A "raw agricultural commodity" is any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing (21 U.S.C. 321(r)). Examples of seafood products that are considered "raw agricultural commodities" are whole, raw uneviscerated fish, whole raw crabs or lobsters, and raw head-on shell-on shrimp. Establishments that solely hold these types of fishery products are exempt from subpart B of 21 CFR part 117, but must still meet the requirements of 21 CFR part 123.

[4] For information regarding jurisdiction of alcoholic beverages, see 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

B.13 Are pet foods or animal feeds subject to the food allergen labeling requirements of the FD&C Act?

No. FDA interprets section 403(w) of the FD&C Act to apply only to foods for human consumption and to not apply to pet foods or animal feeds.

B.14 Are prescription or over-the-counter drugs, cosmetics, or household cleaning products subject to the food allergen labeling requirements of the FD&C Act?

No. FDA interprets section 403(w) of the FD&C Act to apply only to foods intended for human consumption and to not apply to prescription or over-the-counter drugs, cosmetics (such as face powder, body lotion, or bath soap), or household cleaning products (such as laundry detergent).

B.15 Are foods packaged for airline and other transportation carriers subject to the food allergen labeling requirements of the FD&C Act?

Yes. All packaged foods served or sold onboard airlines (including international-bound flights) and other transportation carriers are subject to the mandatory labeling requirements that apply to all packaged foods manufactured in or imported into the United States, including the food allergen labeling requirements in section 403(w) of the FD&C Act. Because these foods must have an ingredient list (see 21 CFR 101.4), the major food allergens could either be declared in the ingredient list, a separate "Contains" statement, or both.

B.16 Are proteins from major food allergens, produced from other sources through the use of genetic engineering and other technologies, subject to the food allergen labeling requirements of the FD&C Act?

Yes. The food allergen labeling requirements of the FD&C Act are intended to protect people with food allergies who cannot determine what major food allergens are in their foods without labeling. Section 201(qq) of 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, soybeans, and sesame and also as a food ingredient that contains protein derived from these foods. Food ingredients that include proteins derived from a major food allergen (e.g., through chemical, biochemical, mechanical, fermentation, or bioengineering processes) may be capable of eliciting an allergic reaction, and their presence is not obvious without declaration of the allergen. An example would be protein that is derived from cow milk but produced via fermentation in a non-milk food source, such as a genetically engineered strain of yeast. In this example, the protein produced by fermentation may be identical (or sufficiently similar) to the protein in milk such that it could be capable of binding to specific antibodies and causing allergic reactions to people sensitive to proteins in milk. We consider these proteins to be "derived from" major food allergens because they are produced in a manner that uses the major food allergen's DNA sequence. FDA recognizes,

---

Promulgation and Enforcement of the Labeling Regulations Promulgated under the Federal Alcohol Administration Act: https://www.fda.gov/about-fda/domestic-mous/distilled-spirits.

however, that additional information may be helpful in some cases to make the relationship to the source ingredient clear, such as "Contains milk-derived protein," and we are available for consultation.

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, cod)
- The specific species of Crustacean shellfish (e.g., crab, lobster, shrimp)
- The specific type of tree nut (e.g., almond, pecans, walnuts)
- Wheat
- Peanuts
- Soybeans
- Sesame

C.1 For purposes of complying with the food allergen labeling requirements of the FD&C Act, what is "milk"?

For purposes of the definition of a "major food allergen" under section 201(qq) of the FD&C Act, FDA considers "milk" as milk from domesticated cows, goats, sheep, or other ruminants. Please also see question B.16.

C.2 How would you declare the milk from animals other than cows as a major food allergen on the label?

Milk from ruminant animals other than cows, when used as an ingredient, must be declared in the ingredient list by common or usual name, such as "goat milk" (section 403(i)(2) of the FD&C Act). For food allergen labeling purposes, milk and milk ingredients from animals other than cows should also include the name of the animal source, such as "goat milk" and "whey (goat milk)" in the ingredient list or "Contains goat milk" in a separate "Contains" statement, or both. FDA recognizes that additional information may be helpful in some cases, and we are available for consultation.

C.3 For purposes of complying with the food allergen labeling requirements of the FD&C Act, what are "eggs"?

For purposes of the definition of a "major food allergen" under section 201(qq) of the FD&C Act, FDA considers "eggs" as eggs from domesticated chickens, ducks, geese, quail, and other fowl. Please also see question B.16.

C.4 How would you declare the presence of eggs from birds other than chickens on the food label?

Eggs from birds other than chickens, when used as an ingredient, must be declared in the ingredient list by common or usual name, such as "duck egg" (see section 403(i)(2) of the FD&C Act). For food allergen labeling purposes, egg and egg ingredients from birds other than chickens should also include the name of the bird source, such as "duck egg" and "ovalbumin (duck egg)" in the ingredient list or "Contains duck egg" in a separate "Contains" statement, or both. FDA recognizes that additional information may be helpful in some cases, and we are available for consultation.

C.5 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 (e.g., 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, walnuts). It also requires that the species be declared for fish (e.g., bass, flounder, cod) and Crustacean shellfish (e.g., crab, lobster, shrimp) (section 403(w)(2) of the FD&C Act). This means that the ingredient list or the "Contains" statement cannot broadly declare "tree nuts," "fish," or "Crustacean shellfish" as the major food allergen.

C.6 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 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.7 For the purpose of complying with the food allergen labeling requirements of the FD&C Act, what are tree nuts?

Under section 201(qq) of the FD&C Act, the definition of a "major food allergen" includes tree nuts. FDA is aware that there is no universally accepted botanical definition of the term "tree nut." Authoritative botanical references use many different botanical terms (e.g., berry, capsule, drupe, fruit, nut, seed) to describe the embryo of a tree that can form into a dry, hard fruit considered to be a tree nut. Sometimes multiple, interchangeable botanical terms are used to describe the same tree nut. The scientific data relevant to assessing the allergenicity of any such individual entity varies greatly, in quantity and quality, across the broad range of foods potentially encompassed by the general term "tree nut."

In addition to the tree nuts specifically cited as examples in the definition of "major food allergen" in section 201(qq) of the FD&C Act (i.e., almonds, pecans, and walnuts), the table below includes those tree nuts for which a robust body of scientific evidence supports their inclusion in the list of tree nuts that FDA considers to be major food allergens.

Table 1. Tree Nuts FDA Considers as Major Food Allergens with Their Common or Usual Names and Scientific Names.

Common or usual name	**Scientific name (Family name is identified in parentheses.)**
Almond	*Prunus dulcis* (Mill.) D.A. Webb (Rosaceae)
Black walnut	*Juglans nigra* L. (Juglandaceae)
Brazil nut	*Bertholletia excelsa* Humb. & Bonpl. (Lecythidaceae)
California walnut	*Juglans californica* S. Watson (Juglandaceae)
Cashew	*Anacardium occidentale* L. (Anacardiaceae)
Filbert/Hazelnut	*Corylus* spp. (Betulaceae)
Heartnut/Japanese walnut	*Juglans ailantifolia* Carriere var. *cordiformis* (Makino) Rehder (Juglandaceae)
Macadamia nut/Bush nut	*Macadamia* spp. (Proteaceae)
Pecan	*Carya illinoinensis* (Wangenh.) K. Koch (Juglandaceae)
Pine nut/Pinon nut	*Pinus spp.* (Pineaceae)
Pistachio	*Pistacia vera L.* (Anacardiaceae)
Walnut (English, Persian)	*Juglans regia L.* (Juglandaceae)

The scientific names for the tree nuts included in the table further clarify their identity. This list uses broad scientific categories and uses the abbreviation "spp." to indicate multiple species within a genus that represent tree nuts known by the corresponding common or usual name.

C.8 Are only the tree nuts listed in Table 1 required to be declared as major food allergens? Should manufacturers declare tree nuts that are used as ingredients but not listed in the table as allergens in the "Contains" statement?

Only the tree nuts listed in Table 1 are considered major food allergens, and, therefore, must meet the food allergen labeling requirements of section 403(w) of the FD&C Act. Because other tree nuts that are not listed in Table 1 do not have a robust body of evidence to support inclusion as a major food allergen, they should not be included in the "Contains" statement even if they are used as ingredients because the "Contains" statement is reserved for major food allergens. Tree nuts used as ingredients, but not listed in Table 1, would still be required to be listed by common or usual name in the ingredient list (21 CFR 101.4).

C.9 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.), Khorasan (*Triticum polonicum* L.), and triticale (x *Triticosecale* ssp. Wittm.).

C.10 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, walnut" rather than "almonds, pecans, walnuts," respectively.

C.11 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?

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 Federal Food, Drug, and Cosmetic Act

D.1 Where are the major food allergens required to be declared on the food label?

The food source of a major food allergen must be declared either in the ingredient list or in a "Contains" statement printed immediately after, or adjacent to, the ingredient list (section 403(w)(1) of the FD&C Act). If the food source is declared in the ingredient list and a "Contains" statement is also used, then the food source of all of the major food allergens

present in the food are to be declared in the "Contains" statement, even if they are declared in the ingredient list (section 403(w)(1) of the FD&C Act). See Figure 4 below.

Figure 4. Examples of three ways that allergens can be declared. In the first example, milk and soy are declared in the "Contains" statement. In the second example, milk and soy are declared as part of the common or usual name of the ingredients, but wheat, egg, and peanut are not, so

they are declared in parentheses after the common or usual name of the ingredient. In the third example, wheat, milk, soy, and peanuts are clearly declared as ingredients or as part of the common or usual name of ingredients, and egg is declared in parentheses next to ovalbumin.

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, sesame, or soybeans may identify the food source from which the major food allergen is derived in the statement of identity (or name of 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.

Figure 2. Example of a single-ingredient food intended for further manufacturing where the "Contains" statement is on the front of the food package.

D.3 Under the food allergen labeling requirements of the FD&C Act, must individual units within a multiunit package have a "Contains" statement if each unit is not fully labeled?

The unit containers in a multiunit or multicomponent retail food package are exempt from certain labeling requirements, including an ingredient statement under 21 CFR 1.24(a)(14); however, such foods are not exempt from allergen labeling requirements. If the food is or contains a major food allergen, a "Contains" statement must be used in order to comply with section 403(w)(1) of the FD&C Act and should be declared near the statement of identity in the absence of an ingredient list.

However, no labeling is needed, including allergen labeling, if the individual unit is an unlabeled inner sleeve intended solely for protection of the product, such as sleeves of crackers, and does not contain any written, printed, or graphic matter.

D.4 If an ingredient contains major food allergens from several different types or species, does each specific type or species need to be declared on the label?

Yes. Under section 403(w)(2) of the FD&C Act, if an ingredient is derived from several different species or types of a major food allergen, each specific type or species must be declared on the label, e.g., "gelatin (cod, haddock, pollock)" or "Contains cod, haddock, pollock."

D.5 Is the name of the food source from which the major food allergen is derived required to be declared in the ingredient list more than once if the food contains multiple ingredients that are or contain the same major food allergen?

No. The name of the food source from which the major food allergen is derived is required to be declared only once in the ingredient statement, even if the food contains multiple ingredients that are or contain that same major food allergen, unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of a food ingredient that is not a major food allergen (see section 403(w)(1)(B)(ii) of the FD&C Act). For example, both sodium caseinate and nonfat dry milk are derived from milk. If the ingredient list identifies sodium caseinate and nonfat dry milk as ingredients, the declaration of "milk" as part of the common or usual name "nonfat dry milk" would be sufficient.

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 the list of ingredients is to identify all three names of the food sources from which the major food allergens are derived (e.g., "Contains milk, egg, peanuts") in the same type (i.e., print or font) size as that used for the ingredient list (see section 403(w)(1) of the FD&C Act).

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 from which all major food allergens are derived 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)(2) 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 As a manufacturer, how do I label a major food allergen that is also an incidental additive? Can ingredients from cross-contact be considered incidental additives?

Incidental additives, including processing aids, are ingredients added to a food that are exempt from being declared in the ingredient list (21 CFR 101.100(a)(3)). However, they are not exempt from the food allergen labeling requirements. Therefore, if an incidental additive is, or bears or contains a major food allergen, you would have to declare the name of the food source from which the major food allergen is derived (section 403(w)(4) of the FD&C Act). For example, if you use wheat flour on the processing belt while processing rice crackers (as a processing aid) and do not declare "wheat" in the ingredient list, then you must list "wheat" in a "Contains" statement (section 403(w)(4) of the FD&C Act). Major food allergens intentionally added to a food must be declared in the ingredient list or in a "Contains" statement (section 403(w)(4) of the FDA&C Act).

Foods that are incidental additives are not the same as substances that are unintentionally present due to cross-contact from shared equipment. Allergens present due to cross-contact are not considered incidental additives. Furthermore, allergens present due to cross-contact are not to be declared in the ingredients list or the "Contains" statement.

D.9 As a manufacturer, how do I label oils derived from a major food allergen?

Highly refined oils, which are intended to signify refined, bleached, deodorized oils, that are derived from major food allergens are exempt from section 403(w) of the FD&C Act. However, under the general ingredient labeling requirements, the source of all oils (whether highly refined

or not) must be included as part of the common or usual name of the oil in the ingredient list (such as "soybean oil") (21 CFR 101.4(b)(14)). If a highly refined oil is exempt from ingredient labeling because it is an incidental additive in accordance with 21 CFR 101.100, there is no additional allergen labeling requirement under the FD&C Act.

If an oil that is derived from a major food allergen is not highly refined, then the source of the oil must be declared on the label in accordance with section 403(w) of the FD&C Act. Such labeling can be accomplished by either declaring the oil by its common or usual name in the ingredient list or declaring the source of the oil in a "Contains" statement, or both.

D.10 May a "Contains" statement be used to alert consumers to the presence of: (a) food allergens other than the major food allergens defined in the FD&C Act; and (b) food substances that are not food allergens to which individuals may be sensitive?

No. The purpose of the "Contains" statement as required by section 403(w) of the FD&C Act is to declare the presence of major food allergens. If the "Contains" statement was used to list: (a) food allergens other than the major food allergens; or (b) food substances that are not food allergens to which individuals may be sensitive, it may become more difficult for consumers to easily determine if a food contains a major food allergen, which would undermine the purpose of the "Contains" statement. Therefore, reserving the use of the "Contains" statement for its intended purpose enhances the clarity and directness of communicating information about the major food allergens for allergic consumers.

However, FDA does not object to voluntary statements about other allergen information that are separate from the "Contains" statement as long as they are truthful and not misleading.

D.11 Is a major food allergen that has been unintentionally incorporated in a food as the result of cross-contact subject to the food allergen labeling requirements of the FD&C Act?

No. The food allergen labeling requirements of the FD&C Act do not apply to a major food allergen that is unintentionally incorporated in a food as a result of cross-contact. In the context of food allergens, "cross-contact" occurs when an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food. Allergens may be unintentionally present in a food as a result of practices such as improper rework addition, product carry-over due to use of common equipment and production sequencing, or the presence of an allergenic product above exposed product lines. This is often referred to as unintended allergen presence.[5]

However, allergen cross-contact is recognized as a potential hazard for consumers. FDA has established requirements for food allergen preventive controls, as well as good manufacturing

[5] "Unintended allergen presence" – this term was adopted to describe the presence of a food allergen due to cross-contact. Allergen cross-contact is the "unintentional incorporation of a food allergen into a food" as defined in the FDA's Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (21 CFR part 117). Title 21 CFR part 117 also defines "food allergen" to mean a major food allergen as defined in section 201(qq) of the FD&C Act.

practices to protect food against food allergen cross-contact, in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulations in 21 CFR part 117. When these measures are not able to completely eliminate allergen cross-contact, some manufacturers have chosen to include allergen advisory statements[6] to warn consumers about potential allergen cross-contact.

D.12 Does section 403(w) of the FD&C Act address the use of allergen advisory statements (such as "may contain")[7]?

No. Section 403(w) of the FD&C Act does not address the use of allergen advisory statements, including statements describing the potential for unintended allergen presence in food products resulting from the manufacturing process or the preparation and packaging of the food in a retail or food service establishment. An allergen advisory statement, such as "may contain [allergen]," is not a substitute for adherence to current good manufacturing practices or food allergen preventive controls and must be truthful and not misleading (section 403(a)(1) of the FD&C Act).

D.13 Can allergen-free claims be made on products?

Yes, firms may place voluntary statements to provide information to consumers that certain allergens are absent from the product (e.g., "allergen-free" claim). There are no regulations defining specific conditions for a product to make a "free" claim from a major food allergen source. If voluntary allergen-free claims are used, they must be truthful and not misleading in accordance with section 403(a)(1) of the FD&C Act. For example, if a product label or labeling were to have a "milk-free" or similar claim, FDA would expect there to be no milk allergen in the product, including unintended milk allergen presence due to cross-contact. In addition, a product with an allergen-free claim should not have an advisory statement that includes the same allergen. For example, a product that has a "may contain milk" statement should not also bear a "milk-free" claim.

D.14 Can a product that is made with a major food allergen as an ingredient, that is declared in the ingredients list or "Contains" statement or both, also have an advisory statement for the same ingredient? For example, can it say "Contains milk" and also say "may contain milk"?

If a product is formulated with a major food allergen as an ingredient and has declared it in the ingredients statement or "Contains" statement or both, it is not appropriate to use an advisory statement for the same major food allergen to alert consumers to its potential presence as an unintentional allergen in the same food product. Since the advisory statement implies that the product is not intended to contain the major food allergen, the purpose of the advisory statement in such situations could be misleading. For example, a product that has a "Contains milk"

[6] Allergen Advisory Statements are often referred to as Precautionary Allergen Labeling (PAL) outside FDA.

statement should not also bear a "may contain milk" statement.

D.15 Is it sufficient to just label my food product with a "may contains" statement due to possible cross-contact?

No. You must follow current good manufacturing practices to protect against allergen cross-contact (see 21 CFR part 117, specifically sections 117.10(b), 117.20(b)(2), 117.35 (d)-(f), 117.40(a)-(b), 117.80(a)-(c), 117.93)). Food facilities that are subject to the preventive controls requirements in 21 CFR part 117 must conduct a hazard analysis and implement a food safety plan that may include allergen controls for proper labeling and the protection of food from allergen cross-contact (see 21 CFR 117.135(c)(2) in the Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food). While allergen advisory statements that are truthful and not misleading may be acceptable in certain circumstances, they cannot be used in lieu of good manufacturing practices and preventive controls.

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 sale 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 2022 FDA Food Code contains provisions regarding food allergens in the model code as well as food allergen information in its annexes, specifically:

- (Part 1-2) Definition of "major food allergen"
- (Part 2-1) Supervision (Knowledge and duties)
- (Part 3-6) Food Identity, Presentation and On-Premises Labeling
- (Part 4-6) Cleaning of Equipment and Utensils
- (Annex 3) Additional information on food allergens
- (Annex 4) Additional information on food allergens
- (Annex 7) Model Forms, Guides and Other Aids

D.18 Do the food allergen labeling requirements of the FD&C Act apply regardless of whether a jurisdiction has adopted the 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 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 of the type but not identical to those in section 403(w) of the FD&C Act (section 403A of the FD&C Act (21 U.S.C. 343-1)).

E. Dietary Supplements

E.1 What types of dietary supplement ingredients are subject to the food allergen labeling requirements of the FD&C Act?

Section 403(w) of the FD&C Act applies to ingredients used to make dietary supplements that are or contain a major food allergen. This includes the following types of ingredients:

- **Dietary ingredient** – defined as, among other things, a vitamin, mineral, herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any such ingredients. Protein, if intended to supplement the diet by increasing the total dietary intake, is an example of a dietary ingredient (see section 201(ff) of the FD&C Act).

- **Source ingredient** – an ingredient that supplies the dietary ingredient. Sodium caseinate (derived from milk) is an example of a source ingredient for the dietary ingredient protein (see 21 CFR 101.36(d)).

- **Other ingredients** – examples of ingredients other than dietary ingredients or source ingredients include processing aids such as excipients, fillers, artificial colors, artificial sweeteners, flavors, or binders (21 CFR 101.4(g)).

E.2 When the major food allergen is already declared within the Supplement Facts label, must the allergen be declared elsewhere on the dietary supplement's label?

Usually not. We will consider the food allergen labeling requirements of the FD&C Act to be satisfied when the major food allergen is declared within a Supplement Facts label. FDA regulations (such as 21 CFR 101.36, 101.4(a)(1), and 101.4(g) and (h)) specify how dietary supplements must be labeled. When a source ingredient that supplies a dietary ingredient is identified in parentheses within the Supplement Facts label, or when the name of the dietary ingredient or its synonym is the source ingredient, it need not be repeated in the ingredient list that appears outside of the Supplement Facts label (see 21 CFR 101.36(d)). The complete listing of ingredients may be determined by consulting both the Supplement Facts label and any ingredient list on the dietary supplement label. If there is a "Contains" statement being used, however, the major food allergen would also need to be declared there so that the "Contains" statement includes all major food allergens in the product.

E.3 Where on the dietary supplement label should a "Contains" statement be printed?

When an ingredient list is present on the dietary supplement label, any "Contains" statement also included on the label must be printed immediately after, or adjacent to, the ingredient list (see section 403(w)(1)(A) of the FD&C Act). However, when the label of a dietary supplement does not include an ingredient list, FDA will consider the food allergen labeling requirements to be satisfied if any "Contains" statement is printed outside and immediately after, or adjacent to, the Supplement Facts label.

E.4 How should manufacturers label a dietary supplement when it contains a dietary ingredient that is or contains a major food allergen, but the name of the dietary ingredient does not identify the major food allergen?

Firms may declare the name of the food source from which the major food allergen is derived as follows to comply with section 403(w) of the FD&C Act:

- Parenthetically within the Supplement Facts label immediately after the name of the dietary ingredient. For example, if the dietary ingredient is bovine colostrum and the allergen is milk, declare "bovine colostrum (milk)" within the Supplement Facts label; or

- Parenthetically in the ingredient list (e.g., "Ingredients: bovine colostrum (milk)…"); or

- Separately in a "Contains" statement printed immediately after, or adjacent to, the ingredient list or the Supplement Facts label (e.g., "Contains Milk").

E.5 How should firms label a dietary supplement when it contains a dietary ingredient which has a source ingredient that is or contains a major food allergen, but the name of the source ingredient does not identify the name of the major food allergen?

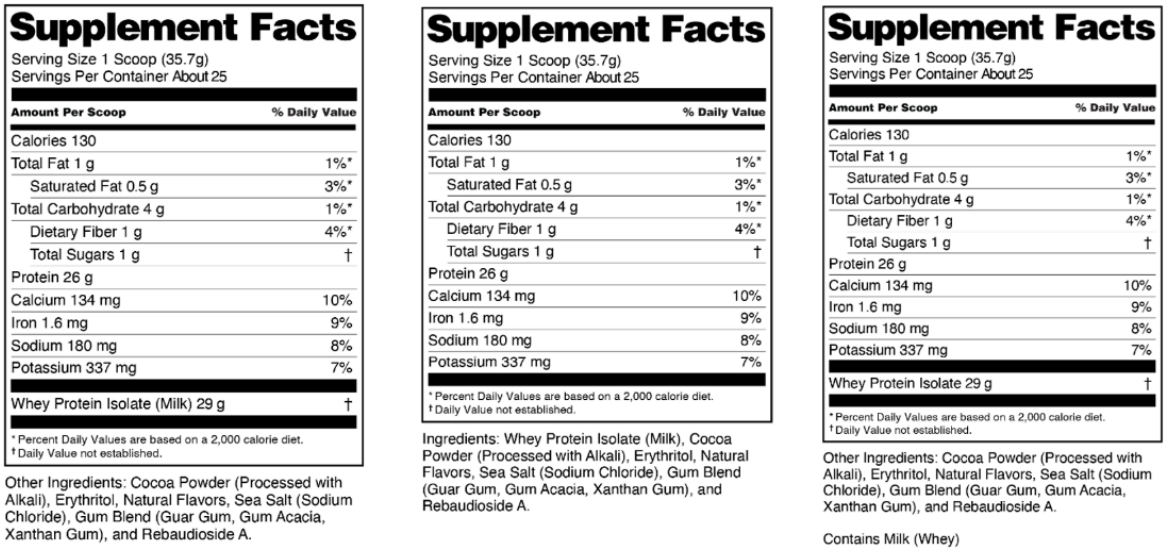
The firm may declare the food source of the major food allergen as follows to comply with section 403(w) of the FD&C Act:

- Parenthetically within the Supplement Facts label immediately after the name of the "source ingredient." For example, if the source ingredient of the dietary ingredient protein is sodium caseinate, declare "protein (as sodium caseinate) (milk)" within the Supplement Facts label; or

- Parenthetically in the ingredient list (e.g., "Ingredients: sodium caseinate (milk)…"); or

- Separately in a "Contains" statement printed immediately after, or adjacent to, the ingredient list or the Supplement Facts label (e.g., "Contains Milk").

See Figure 6 below for examples.



Supplement Facts
Serving Size 1 Scoop (35.7g)
Servings Per Container About 25

Amount Per Scoop	% Daily Value
Calories 130	
Total Fat 1 g	1%*
Saturated Fat 0.5 g	3%*
Total Carbohydrate 4 g	1%*
Dietary Fiber 1 g	4%*
Total Sugars 1 g	†
Protein 26 g	
Calcium 134 mg	10%
Iron 1.6 mg	9%
Sodium 180 mg	8%
Potassium 337 mg	7%
Whey Protein Isolate (Milk) 29 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other Ingredients: Cocoa Powder (Processed with Alkali), Erythritol, Natural Flavors, Sea Salt (Sodium Chloride), Gum Blend (Guar Gum, Gum Acacia, Xanthan Gum), and Rebaudioside A.

Supplement Facts
Serving Size 1 Scoop (35.7g)
Servings Per Container About 25

Amount Per Scoop	% Daily Value
Calories 130	
Total Fat 1 g	1%*
Saturated Fat 0.5 g	3%*
Total Carbohydrate 4 g	1%*
Dietary Fiber 1 g	4%*
Total Sugars 1 g	†
Protein 26 g	
Calcium 134 mg	10%
Iron 1.6 mg	9%
Sodium 180 mg	8%
Potassium 337 mg	7%

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Ingredients: Whey Protein Isolate (Milk), Cocoa Powder (Processed with Alkali), Erythritol, Natural Flavors, Sea Salt (Sodium Chloride), Gum Blend (Guar Gum, Gum Acacia, Xanthan Gum), and Rebaudioside A.

Supplement Facts
Serving Size 1 Scoop (35.7g)
Servings Per Container About 25

Amount Per Scoop	% Daily Value
Calories 130	
Total Fat 1 g	1%*
Saturated Fat 0.5 g	3%*
Total Carbohydrate 4 g	1%*
Dietary Fiber 1 g	4%*
Total Sugars 1 g	†
Protein 26 g	
Calcium 134 mg	10%
Iron 1.6 mg	9%
Sodium 180 mg	8%
Potassium 337 mg	7%
Whey Protein Isolate 29 g	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other Ingredients: Cocoa Powder (Processed with Alkali), Erythritol, Natural Flavors, Sea Salt (Sodium Chloride), Gum Blend (Guar Gum, Gum Acacia, Xanthan Gum), and Rebaudioside A.

Contains Milk (Whey)

Figure 6: Example of a dietary supplement declaring the major food allergen "milk" within the supplement facts panel, in the ingredient list, or in the "Contains" statement.

E.6 For other ingredients in dietary supplements, where do firms declare the major food allergen?

For other ingredients (such as an excipient, filler, binder, or flavor) that are not dietary or source ingredients, the food source name of the major food allergen must be declared either in an ingredient list or in a separate "Contains" statement, or both, in accordance with section 403(w)(1) of the FD&C Act.

E.7 Must a separate "Contains" statement be provided on the label of a dietary supplement if all major food allergens are declared either within the Supplement Facts label or in an ingredient list?

No. A separate "Contains" statement is not needed if the major food allergens are declared either within the Supplement Facts label or in an ingredient list (section 403(w) of the FD&C Act). However, if a "Contains" statement is used, the source of all of the major food allergens in the dietary supplement are to be included in the "Contains" statement.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

The time required to complete this information collection is estimated to average 17 hours per response for third-party disclosure activities associated with sesame and average 168 hours per response for reporting activities associated with sesame, which includes the time to review instructions, search existing data sources, gather the data needed, and complete and review the

information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Office of Nutrition and Food Labeling
Human Foods Program
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-1450

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

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0792. To find the current expiration date, search for this OMB control number at https://www.reginfo.gov/public/do/PRAMain.