

Sec. 555.250 Major Food Allergen Labeling and Cross-contact Draft Compliance Policy Guide

Guidance for FDA Staff

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at CFSANCompliancePolicy@FDA.HHS.GOV.

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

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Sec. 555.250 Major Food Allergen Labeling and Cross-contact Draft Compliance Policy Guide Guidance for FDA Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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

The purpose of this compliance policy guide (CPG) is to provide guidance for FDA staff on FDA's enforcement policy regarding major food allergen labeling and cross-contact. See section II.B for more information about major food allergens, which are defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(qq)).

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. Background

A. Food Allergies

Food allergies affect millions of Americans and their families. Each year, FDA receives reports about consumers who experienced adverse reactions following exposure to hazards posed by food allergens. A food allergen is the food or component(s) (often a protein) of a food that elicit specific immunologic reactions. Food allergies are abnormal responses of the immune system to foods that most individuals can eat safely. While many different types of food allergies have been identified, food allergies that are recognized to be the most severe and immediately life-threatening are those that are mediated by immunoglobulin E (IgE) antibodies.

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Adverse allergic reactions may result from a single eating occasion of the food allergen and can vary in severity from self-limiting gastrointestinal symptoms or skin rashes to severe symptoms of anaphylaxis, which may include wheezing, laryngeal edema, and/or shock and can be fatal. There are currently no effective treatments for preventing all allergic reactions from food allergen exposures; thus, to prevent adverse health consequences, food allergic consumers need to be able to identify and avoid food allergen hazards.

B. Definition of Major Food Allergens

Section 201(qq)(1) of the FD&C Act (21 U.S.C. 321(qq)(1)) defines a major food allergen, in part, as any of the following:

- 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.

Section 201(qq)(2)(A) of the FD&C Act (21 U.S.C. 321(qq)(2)(A)) excludes highly refined oils¹ derived from one of the major food allergens and any ingredient derived from highly refined oils from the definition of major food allergen. Also, raw agricultural commodities such as fresh fruits and vegetables in their natural state are not subject to the allergen labeling requirements under section 403(w) of the FD&C Act (21 U.S.C. 343(w)).

Section 201(qq)(2)(B) of the FD&C Act (21 U.S.C. 321(qq)(2)(B)) excludes a food ingredient that is exempt under sections 403(w)(6) and (7) of the FD&C Act (21 U.S.C. 343(w)(6) and (7)) from the definition of major food allergen. Under section 403(w)(6) of the FD&C Act (21 U.S.C. 343(w)(6)), a person may submit a petition to FDA to exempt a food ingredient from the allergen labeling requirements. The burden is on the petitioner to provide evidence that the food ingredient does not cause an allergic response that poses a risk to human health (403(w)(6)(C) of the FD&C Act (21 U.S.C. 343(w)(6)(C))). Under section 403(w)(7) of the FD&C Act (21 U.S.C. 343(w)(7)), a person can file a notification establishing that the food ingredient does not contain

¹ The Senate Report 108-226 that accompanied the Food Allergen Labeling and Consumer Protection Act of 2004 stated that “highly refined oils” are “intended to signify refined, bleached, deodorized oils.” Senate Report 108-226 is available at: <https://www.congress.gov/congressional-report/108th-congress/senate-report/226>

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allergenic protein. Food allergen petitions² and notifications³ submitted under sections 403(w)(6) and (7) of the FD&C Act (21 U.S.C. 343(w)(6) and (7)) and FDA’s responses are posted on FDA’s website.

C. Labeling Requirements Applicable to Major Food Allergens⁴

Major food allergens used as ingredients in packaged foods and regulated under the FD&C Act must be declared by the name of the food source from which the major food allergen is derived either in the ingredient list or the “Contains” statement (section 403(w) of the FD&C Act (21 U.S.C. 343(w))). The ingredient list on a food label is the listing of each ingredient in descending order of predominance by weight (21 CFR 101.4). The “name of the food source from which the major food allergen is derived” means the name described in section 201(qq)(1) of the FD&C Act (21 U.S.C. 321(qq)(1)), provided that, in the case of a tree nut, fish, or Crustacean shellfish, the term means the name of the specific type of nut or species of fish or Crustacean shellfish (section 403(w)(2) of the FD&C Act (21 U.S.C. 343(w)(2))). The use of both the ingredient list and the “Contains” statement for declaration of the presence of major food allergens is limited to major food allergen ingredients in a food.

For food that is made from two or more ingredients, the label must bear the common or usual name of each such ingredient (section 403(i)(2) of the FD&C Act (21 U.S.C. 343(i)(2))). For major food allergens, if the common or usual name of the ingredient does not include the name of the food source from which the major food allergen is derived, food allergen labeling requirements may be met if the name of the ingredient is followed in parenthesis by the name of the food source, e.g., “whey (milk).” However, the name of the food source is not required when the common or usual name of the ingredient uses the name of the food source from which the major food allergen is derived (e.g., buttermilk) or if the name of the food source appears elsewhere in the ingredient list as part of the name of a food ingredient that is a major food allergen (e.g., whey would not need to include “(milk)” in the ingredient list if buttermilk is listed as another ingredient) (section 403(w)(1)(B) of the FD&C Act (21 U.S.C. 343(w)(1)(B))).

The food allergen labeling requirements also may be met by using a “Contains” statement immediately after or adjacent to the ingredient list with the name of the food source from which the major food allergen is derived (section 403(w)(1)(A) of the FD&C Act (21 U.S.C. 343(w)(1)(A))). If a “Contains” statement is used on a food label, then the food

² Inventory of petitions received under section 403(w)(6) of the FD&C Act (21 U.S.C. 343(w)(6)) for exemptions from food allergen labeling, available at: [Inventory of Petitions Received under 21 U.S.C. 343\(w\)\(6\) for Exemptions from Food Allergen Labeling | FDA](#).

³ Inventory of notifications received under section 403(w)(7) of the FD&C Act (21 U.S.C. 343(w)(7)) for exemptions from food allergen labeling, available at: <https://www.fda.gov/food/food-labeling-nutrition/inventory-notifications-received-under-21-usc-343w7-exemptions-food-allergen-labeling>.

⁴ For more information on food allergens, including labeling requirements, see FDA Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5).

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source of all major food allergens present in the food are to be declared in the “Contains” statement, even if they are already declared in the ingredient list.⁵

With some exceptions, FDA regulations allow the use of collective terms for specific ingredients and exempt the labeling of incidental additives in the ingredient list. For example, spices, natural flavor, and artificial flavor may be declared using a collective term (e.g., “spice,” “natural flavor,” or “artificial flavor,” respectively) without identifying the particular spice or flavor (21 CFR 101.22(h)(1)). Additionally, some colorings may be declared using a collective term, e.g., “Color Added” (see 21 CFR 101.22(k)(2)). Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food are exempt from the ingredient declaration requirements (see 21 CFR 101.100(a)(3)). However, a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen is subject to the labeling requirements of section 403(w) of the FD&C Act (21 U.S.C. 343(w)); therefore, in such cases, the label must identify the food source of the major food allergen, e.g., natural flavor (milk) (section 403(w)(4) of the FD&C Act or 21 U.S.C. 343(w)(4)). Additionally, if sesame is used as an ingredient as part of a spice blend and is declared using the collective term “spice” or “spices,” in accordance with section 403(i) of the FD&C Act, such that its common or usual name does not appear in the ingredient list, it is to 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).”

D. Allergen Cross-contact and Manufacturing Requirements Applicable to Preventing Cross-contact due to Major Food Allergens

Allergen cross-contact is the unintentional incorporation of a food allergen into a food as defined in FDA’s rule titled, “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” in 21 CFR part 117 (“part 117”). Part 117 defines “food allergen” to mean a major food allergen as defined in section 201(qq) of the FD&C Act (21 U.S.C. 321(qq)). Allergen cross-contact occurs between foods that have different food allergen profiles (i.e., the food allergen sources present or absent in a food).

Allergen cross-contact may occur due to practices such as failure to adequately clean shared equipment, failure to properly segregate allergens, improper rework addition, or improper production scheduling. The likelihood of unintended allergen presence (i.e., presence of an allergen due to cross-contact) can be impacted by various factors, such as the characteristics of the food, the distribution of the allergen within a food (homogeneous versus particulate), the type of manufacturing process, equipment used, and the cleaning procedures applied (e.g., dry cleaning versus wet cleaning).

⁵ FDA may regard a product to be misbranded under section 403(a)(1) of the FD&C (21 U.S.C. 343(a)(1)) when the food source of all major food allergens used as ingredients are declared in the ingredient list but the “Contains” statement also present on the label does not list the food source of all major food allergens. See section III.C. (Incomplete or inconsistent allergen information).

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The food allergen labeling requirements of the FD&C Act only apply to a major food allergen that is an ingredient of the product (see Section II. C). Major food allergens unintentionally incorporated into a food are not to be declared in the ingredient list or the “Contains” statement. Instead, firms must comply with applicable requirements to address allergen cross-contact. Part 117 establishes requirements applicable to establishments that manufacture, process, pack, or hold human food. Part 117 includes current good manufacturing practice (CGMP) requirements (primarily in subpart B, with associated requirements in subparts A and F) to prevent allergen cross-contact. Part 117 also establishes specific requirements (commonly called “preventive controls requirements”; primarily in subparts C and G, with associated requirements in subparts A, D, E, and F) for domestic and foreign facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) to establish and implement hazard analysis and risk-based preventive controls for human food as mandated by section 418 of the FD&C Act (21 U.S.C. 350g). With a few exceptions, these preventive controls requirements specify that food facilities must implement a food safety plan that includes a hazard analysis to identify known or reasonably foreseeable hazards that require a preventive control (see 21 CFR 117.126). Preventive controls must significantly minimize or prevent hazards (see 21 CFR 117.135). When a hazard requiring a preventive control is a major food allergen, preventive controls must ensure that the food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act (21 U.S.C. 342(a)) or misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) (see 21 CFR 117.135). For example, inadequate sanitation control, such as failure to adequately clean shared equipment between production runs of products with different allergen profiles to significantly minimize or prevent allergen cross-contact, may render the product adulterated under section 402(a)(4) of the FD&C Act (21 U.S.C. 342(a)(4)). As another example, inadequate allergen label controls, such as failure to check the product label to ensure major food allergen ingredients intended to be in the food are labeled as required, may result in a product misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)).

Part 117 provides for several exemptions from the preventive controls requirements. For example, the preventive controls requirements do not apply to a facility that is a qualified facility as defined in part 117 (see 21 CFR 117.5(a)). As another example, the preventive controls requirements do not apply with respect to activities that are subject to hazard analysis and critical control point (HACCP) requirements in 21 CFR part 120 (for juice) or 21 CFR part 123 (for seafood) if a facility is required to comply with, and is in compliance with, 21 CFR part 120 or 21 CFR part 123, respectively, with respect to such activities (see the exemptions in 21 CFR 117.5(b) and (c)). However, qualified facilities and juice and seafood processors must address major allergens cross-contact through the application of CGMPs (see 21 CFR 117 subpart B). Juice and seafood processors should

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also consider allergen cross-contact under the standard sanitary operational procedures or in the HACCP plan under 21 CFR parts 120 and 123, respectively.⁶

E. Voluntary Allergen Information on Food Products (e.g., Allergen Advisory Statements and Allergen-free Claims.)

Separate from the food allergen labeling requirements of the FD&C Act, firms may voluntarily place other information or statements on the labels of food products to disclose information about allergens to consumers. For example, firms may choose to voluntarily place allergen advisory statements⁷ on products to alert consumers to the possible presence of major food allergens due to cross-contact. Some examples of allergen advisory statements include, “may contain [allergen],” or “produced in a facility that also uses [allergen].” Allergen advisory statements are not a substitute for adherence to current good manufacturing practices and, when used by a facility, food allergen preventive controls. In addition, any allergen advisory statement must be truthful and not misleading (section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1))).

Firms also may place voluntary statements to provide information to consumers that certain allergens are absent from the product (e.g., “allergen-free” claim). Other than the term “gluten-free” which is defined in 21 CFR 101.91,⁸ there are no regulations defining specific conditions (e.g., allergen levels) 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 (21 U.S.C. 343(a)(1)). 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.

III. Policy

Allergen violations may be due to failure to meet allergen labeling requirements, lack of adequate controls to significantly minimize or prevent allergen cross-contact, or incomplete or inconsistent allergen information on the label. Our regulatory approach in addressing allergen violations will be case-by-case and dependent on the facts of each situation.

A. Undeclared allergen/misbranding:

FDA generally regards a product to be misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) when:

⁶ For additional information, see FDA guidance documents: Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition; Guidance for Industry: Juice HACCP and the FDA Food Safety Modernization Act; Fish and Fishery Products Hazards and Controls, Fourth Edition; and Guidance for Industry: Seafood HACCP and the FDA Food Safety Modernization Act

⁷ Allergen advisory statements are also known as precautionary allergen labeling (PAL).

⁸ Enforcement policy related to the gluten-free labeling requirements (21 CFR 101.91) is outside the scope of this CPG.

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The food is formulated to contain a major food allergen as an ingredient and fails to declare on the label the major food allergen by the name of the food source from which the major food allergen is derived in either the ingredient list or the “Contains” statement as required.

FDA generally regards a product to be misbranded under section 403(i)(2) of the FD&C Act (21 U.S.C. 343(i)(2)) when:

The food is fabricated from two or more ingredients but fails to declare on the label the common or usual name of the ingredient in the ingredient list as required.

B. Allergen cross-contact/adulteration:

FDA generally regards a product to be adulterated under section 402(a)(4) of the FD&C Act (21 U.S.C. 342(a)(4)) when case-by-case review of the evidence, including inspectional evidence or other information, demonstrates that allergen cross-contact may render the product injurious to health.

When there is evidence of inadequate allergen cross-contact controls, FDA may deem a product adulterated under section 402(a)(4) of the FD&C Act (21 U.S.C. 342(a)(4)), even when the product bears an allergen advisory statement.

C. Incomplete or inconsistent allergen information/misbranding:

FDA generally regards a product to be misbranded under section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1)) when case-by-case review of the evidence shows incomplete or inconsistent product information regarding major food allergens to be false or misleading.

IV. Regulatory Action Guidance

A. General Approach

The discussion in this section represents criteria for recommending domestic or import regulatory action to CFSAN, Office of Compliance, Division of Enforcement (HFS-605), the Office of Regulatory Affairs (ORA's) Office of Human and Animal Food Operations (OHAFO), or the Office of Import Operations (OIO). When appropriate, FDA staff should consult CFSAN through the Office of Compliance, Compliance Policy Staff (HFS-605) for questions relating to allergen health hazard.⁹

⁹ FDA has not established a threshold for any major food allergen. However, FDA recognizes that published data on population threshold dose responses to various food allergens are becoming available and that these published data are beginning to raise the possibility that some low-level exposures to some major food allergens may not pose a health hazard to the majority of food allergic individuals.

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If an allergen misbranding or adulteration situation presents a reasonable likelihood of serious adverse health consequences or death to humans or animals, immediate action to remove the food from commerce should be considered. If the firm does not initiate a voluntary recall, FDA will consider other appropriate actions to remove product from commerce, such as mandatory recall or administrative detention. When appropriate, FDA may also consider suspension of facility registration.

Field staff should pay particular attention to situations where allergens are added as intended ingredients of food but not declared on the label as required, or situations where allergen cross-contact may occur because of poor CGMPs, inadequate preventive controls, or inadequate controls under the juice or seafood HACCP regulations.

If the origin of allergen presence or possible presence (e.g., detected by testing or suspected because of adverse consumer reaction(s), respectively) in the product is not known, it may be necessary to follow up with the firm to obtain additional information (e.g., product formulation, ingredient information, and information about other products made on the same line or in the same process environment) to understand whether the allergen was added as an intended ingredient or was present due to cross-contact.

Field staff should also contact CFSAN/Office of Compliance/Division of Enforcement if: 1) the label includes incomplete or inconsistent allergen information; or 2) the firm provides information (e.g., notification or petition for exemption from food allergen labeling) to justify not labeling major food allergens.

When appropriate, important information to be collected and sent to CFSAN for review includes:

- Product label (all sides), including the statement of identity, ingredient list, “Contains” statement, any voluntary statements (e.g., allergen advisory statement,¹⁰ and allergen-free claims), serving size, and net quantity statement;
- Pictures of product with and without packaging;
- Relevant product formulation and processing information;
- FDA or state inspectional evidence or compliance actions, including historical information if appropriate;
- Analytical testing results (e.g., testing done by FDA, state, firm, or private labs) and information related to the testing (e.g., methodology, sample description,

¹⁰ While allergen advisory statements are not the same as allergen labeling, survey data in North America suggest that these statements may deter some food allergic consumers from consuming the product. Thus, presence of allergen advisory statements may be considered a health risk mitigating factor when allergen cross-contact is appropriately managed consistent with CGMPs, preventive controls, or other controls (e.g., HACCP).

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number and size of samples taken, lot information, location of the sample taken, and likely source of allergen);

- Information or evidence submitted by firm (e.g., product information, manufacturing information, health hazard information, or risk assessment); and/or
- Consumer adverse reactions, complaints, or other issues about the product reported to FDA by the firm, consumers, or other stakeholders.

B. Undeclared allergen/misbranding

Labeling violation occurs when the food is formulated to contain a major food allergen as an ingredient and the label does not declare the major food allergen in either the ingredient list or in a “Contains” statement in accordance with section 403(w) of the FD&C Act (21 U.S.C. 343(w)). Examples may include:

- The product label declares an ingredient (e.g., whey) derived from a major food allergen, but the label does not declare the food source of the major food allergen (e.g., milk) in either the ingredient list or in a separate “Contains” statement.
- The product formulation includes an ingredient containing a major food allergen as a component of a food that can be declared in the ingredient list using a collective term (e.g., a flavoring, coloring, or spice) or as an incidental additive, but fails to declare the food source of the major food allergen, including sesame, in either the ingredient list or in a separate “Contains” statement.

Labeling violations also occur when the food is formulated to contain a major food allergen and the label does not declare the major food allergen ingredient or the food source of the major food allergen in accordance with section 403(i)(2) and section 403(w) of the FD&C Act, respectively (21 U.S.C. 343(i)(2) and 343(w), respectively). For example:

- The product formulation contains an allergen-containing ingredient (e.g., whey), but the label neither declares the common or usual name of the ingredient (e.g., whey) in the ingredient list, nor is the major food allergen (e.g., milk) declared in either the ingredient list or in a separate “Contains” statement.
- The product declares an ingredient (e.g., mayonnaise) that is comprised of sub-ingredients, at least one of which is a major food allergen (e.g., egg), but the label fails to declare the major food allergen (e.g., egg) either in the ingredient list or in a separate “Contains” statement.
- The product label declares “tree nut,” “fish,” or “Crustacean shellfish,” but fails to declare the type of tree nut (e.g., cashews), the species of fish (e.g., tilapia), or

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the species of Crustacean shellfish (e.g., crab), respectively, in either the ingredient list or in a separate “Contains” statement.

- The product label fails to declare the correct type of tree nut, the correct species of fish, or the correct species of Crustacean shellfish in either the ingredient list or in a separate “Contains” statement. For example, the only major food allergen declared in the ingredient list or the “Contains” statement is pistachios, but the only major food allergen in the product formulation is actually cashews.

C. Allergen cross-contact /adulteration

Adulteration due to allergen cross-contact occurs when inspectional evidence or other information indicates that the firm does not have appropriate CGMPs, preventive controls, or other controls (e.g., HACCP) to significantly minimize or prevent allergen cross-contact. This includes:

- Inadequate CGMPs that resulted in failure to ensure that personnel practices, plant equipment and utensils, and other activities do not lead to allergen cross-contact;
- Inadequate sanitation controls (e.g., cleaning) that resulted in allergen cross-contact from shared equipment or utensils;
- Inadequate food allergen controls (e.g., lack of controls during ingredient or product storage, handling, and use) that resulted in cross-contact; and
- Not addressing allergen cross-contact under the juice or seafood HACCP regulations when necessary (e.g., either through the standard sanitary operational procedures or the HACCP plan).

When there is no inspectional evidence, FDA will consider a variety of factors, such as information from the firm, levels of allergen found, product labeling, consumer adverse events, and other relevant information.

When analytical testing results are available for unintended allergen presence, consult with the CFSAN/Office of Compliance/Compliance Policy Staff on the health hazard posed by the product. Case-by-case evidence review will include several factors in determining allergen health hazard posed by unintended allergen presence, such as:

- Estimated exposure to unintended allergen presence per eating occasion. This will be based on information on the level of the allergen or the percent usage of allergen in product and estimated amount of product consumed per eating occasion to estimate an amount of allergen (in gram amounts) consumed per eating occasion;

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- Likelihood of product consumption by allergic consumers and any mitigating allergen information on product; and
- Other evidence if available and as appropriate, such as evidence of insanitary practices, type of allergen control problem resulting in cross-contact, characteristics of allergen residues due cross-contact (e.g., particulates, dusts, etc.), and consumer adverse reaction(s) associated with product.¹¹

D. Incomplete or inconsistent allergen information/misbranding

Incomplete or inconsistent allergen information occurs when there are discrepancies in allergen information on the label. Examples include:

- The food is formulated to contain a major food allergen ingredient and has a “Contains” statement; however, the major food allergen is only declared in the ingredient list but is not declared in the “Contains” statement;
- The food bears an allergen-free type of claim, but there is evidence (e.g., label statement, visual evidence, inspectional evidence, or analytical testing results) to suggest that the food contains that specific major food allergen; and
- Other incomplete or inconsistent allergen information on the label. This will be determined based on case-by-case review of available information, such as product label, product information, evidence of major food allergen presence, adverse event reports, and other factors.

V. Specimen Charges

Domestic Action

Allergen labeling

The article is misbranded within the meaning of section 403(w) of the FD&C Act (21 U.S.C. 343(w)), in that the label fails to declare all major food allergens present in the product, namely [insert the undeclared major food allergen(s)], as required by section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)).

Ingredient declaration

The article is misbranded within the meaning of section 403(i)(2) of the FD&C Act (21 U.S.C. 343(i)(2)), in that it is fabricated from two or more ingredients, and its label fails to bear the common or usual name of each such ingredient.

¹¹ In general, if the product is associated with adverse reactions in allergic consumers, this provides some evidence of unintended allergen presence or allergen hazard in product or that that labeling information or other factors did not effectively mitigate health risk from exposure to the allergen hazard in the product.

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False or Misleading

The article is misbranded within the meaning of section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1)), in that the labeling is false or misleading.

Manufacturing conditions

The article is adulterated within the meaning of section 402(a)(4) of the FD&C Act (21 U.S.C. 342(a)(4)), in that it has been prepared, packed, and held under insanitary conditions whereby it may have been rendered injurious to health.

Import Refusal

Allergen labeling

The article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)) in that it appears to be misbranded within the meaning of section 403(w) of the FD&C Act (21 U.S.C. 343(w)) in that it appears that the label fails to declare all major food allergens present in the product, namely [insert the undeclared major food allergen(s)] as required by section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)).

Ingredient declaration

The article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)) in that it appears to be misbranded within the meaning of section 403(i)(2) of the FD&C Act (21 U.S.C. 343(i)(2)) in that it appears the food is fabricated from two or more ingredients and the label does not list the common or usual name of each such ingredient.

False or Misleading

The article is subject to refusal of admission pursuant section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)) in that it appears to be misbranded within the meaning of section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1)) because the labeling appears to be false or misleading.

Manufacturing conditions

The article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)) in that it appears to be adulterated within the meaning of section 402(a)(4) of the FD&C Act (21 U.S.C. 342(a)(4)) because it appears that the food was prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

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