July 26, 2023

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President
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Via email: ssorscher@cspinet.org and plurie@cspinet.org

Re: Docket No. FDA-2023-P-0342

Dear Dr. Lurie and Ms. Sorscher:

This letter responds to your citizen petition requesting that the Food and Drug Administration (FDA or we) take the following actions:

1. "Issue a notice to manufacturers, similar to [FDA's] June 1996 "Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers," declaring that companies cannot meet their obligation to control allergen cross-contact risks by adding major food allergens intentionally to foods;"
2. "Finalize [FDA's] "Draft Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling (Edition 5)"…to likewise reflect the policy that companies cannot add major food allergens to mitigate cross-contact risks;" and
3. "Clarify in guidance that while cross-contact risks can be declared voluntarily in a 'may contains' advisory statement, they cannot be declared by naming the allergen in the 'Contains' statement or ingredient list, as these are reserved for declaring actual ingredients."

See Citizen Petition from Sarah Sorscher, JD/MPH, Director of Regulatory Affairs, and Peter Lurie, MD/MPH, President, Center for Science in the Public Interest (CSPI), dated January 30, 2023, sent to Robert M. Califf, MD, Commissioner, Food and Drug Administration ("Petition"), at pages 2 through 3.[1]

For the reasons stated below and in accordance with 21 CFR 10.30, FDA is denying your Petition in part and granting it in part.

I. Legal Background and Regulatory Framework of Sesame Allergen Labeling

[1] Although your petition cited 21 U.S.C. § 350g, 5 U.S.C. § 553(e), 21 C.F.R. § 117.135, and 10 C.F.R. § 10.30, we note that 10 C.F.R. 10.30 pertains to a regulation issued by the Nuclear Regulatory Commission. We presume that you meant 21 C.F.R. 10.30 and have treated your petition as a citizen petition, accordingly.

A. Legal Background

Section 403 of the Federal Food, Drug, and Cosmetic (FD&C Act) (21 U.S.C. 343) describes the circumstances under which a food is deemed misbranded. Under section 403(w) of the FD&C Act (21 U.S.C. 343(w)), a food other than a raw agricultural commodity is misbranded if it is or it contains an ingredient that bears or contains a major food allergen and the specified labeling requirements are not met. 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.

B. Regulatory Framework

Several regulations address certain aspects of the misbranding provisions of the FD&C Act and also specify some special circumstances that may be relevant to some food allergens. For example, a food label must bear the common or usual name of the food, if it has one, and the common or usual name of each ingredient if the food is made from two or more ingredients (section 403(i) of the FD&C Act (21 U.S.C. 343(i))).

With respect to food production, our regulation entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (21 CFR part 117; "part 117") establishes requirements applicable to establishments that manufacture, process, pack, or hold human food. Part 117 includes current good manufacturing practice (CGMP) requirements to prevent allergen cross-contact. Allergen cross-contact occurs between foods that have different food allergen profiles (the food allergen sources present or absent in a food). Part 117 also establishes specific requirements (commonly called "preventive controls requirements") for domestic and foreign facilities that must register under section 415 of the FD&C Act to establish and implement hazard analysis and risk-based preventive controls for human food as mandated by the FDA Food Safety Modernization Act of 2011 (FSMA). These preventive controls requirements specify that food manufacturers (with a few exceptions) must implement a food safety plan that includes a hazard analysis to identify known or reasonably foreseeable hazards that require a preventive control. Preventive controls must significantly minimize or prevent hazards. When a hazard requiring a preventive control is a major food allergen, preventive controls also 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 or misbranded under section 403(w) of the FD&C Act. (See 21 CFR 117.126, 117.130(a)(1) and (b)(1)(ii), and 117.135(a)(1), (c)(2), and (c)(3).)

II. Petition Summary and FDA's Response

Your Petition makes three requests of FDA. We discuss these requests and our response to each in the sections that follow. As Requests 1 and 2 are substantially similar, we have combined the discussion of those requests.

A. Request No. 1: FDA should issue a notice to manufacturers declaring that companies cannot meet their obligation to control allergen cross-contact risks by adding major food allergens intentionally to foods; Request No. 2: FDA should finalize FDA's Draft Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling (Edition 5) to likewise reflect the policy that companies cannot add major food allergens to mitigate cross-contact risks

Your Petition requests that the FDA "issue a notice to manufacturers, similar to the agency's June 1996 "Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers," declaring that companies cannot meet their obligation to control allergen cross-contact risks by adding major food allergens intentionally to food" (Petition at pages 2 through 3). Your Petition states that certain manufacturers are "intentionally adding sesame to products instead of implementing…preventive controls" and asserts that "[t]his addition of allergens has the potential to increase risks for sesame-allergic consumers, the very opposite of what the FASTER Act intended" (Petition at page 2). Your Petition includes examples of companies who have either publicly or privately shared that they have added sesame to their products in response to the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act). It also includes examples of products that now include sesame seeds or sesame flour in their ingredient list, where prior versions did not. Your Petition states that this practice is "illegal, violating both the letter and intent of FDA's food safety rules, because it takes an existing hazard identified by the company (an allergen cross-contact risk) and further elevates the risk to consumers by increasing potential exposure to the food allergen" (Petition at page 2).

Your Petition also requests that FDA "finalize its 'Draft Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling (Edition 5)"…to likewise reflect the policy that companies cannot add major food allergens to mitigate cross-contact risks" (Petition at page 3). Your Petition states that this policy "would not serve as a blanket prohibition on the addition of new major food allergens to food…Instead, we expect it to curb the practice of adding major allergens *as a measure to address cross-contact risks and prevent recalls*" (Petition at page 12 (emphasis in original)).

We recognize that food allergies are a complex public health issue affecting millions of people. FDA enforces laws and regulations applicable to labeling and control of food allergens. We expect firms to adhere to good manufacturing practices and preventive controls designed to significantly minimize or prevent the unintentional incorporation of major food allergens into foods not formulated to contain those food allergens as ingredients. For major food allergens, the FD&C Act requires that food labels identify the food source of all major food allergens used to make the food (21 U.S.C. 343(w)). FDA's labeling regulations in general (21 CFR 101.4)

require that ingredients used to make up a food be declared by their common or usual name in descending order of predominance by weight.

We are aware that some manufacturers are intentionally adding sesame to products that previously did not contain sesame and might be doing so for reasons related to allergen cross-contact controls. Although FDA does not encourage the addition of sesame as an ingredient to a food when sesame is not normally an ingredient used to make the food, a company's decision to add sesame and then declare it on the label as required is not violative.

For these reasons, we deny these requests to issue a notice to manufacturers as well as to finalize in guidance a policy that companies cannot add major food allergens to mitigate cross-contact risks. We recognize that this practice could make it more difficult for sesame allergic consumers to find foods that are safe for them to consume, an outcome that FDA does not support. Therefore, we intend to look for opportunities where we can provide guidance in this area, such as practices FDA would recommend to mitigate cross-contact risks. For example, we announced on FDA's website titled, "Foods Program Guidance Under Development" our intent to issue by the end of this calendar year a draft guidance titled "Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 11: Food Allergen Controls" (https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/foods-program-guidance-under-development). The draft guidance will provide for public comment; we encourage you to review this draft guidance, once issued, and submit comments. We will continue engaging both industry and consumer stakeholders such as CSPI on these issues moving forward in order to explore other opportunities that could help consumers who are allergic to sesame find foods that are safe for them to consume.

B. Request No. 3: FDA should clarify in guidance that while cross-contact risks can be declared voluntarily in a "may contains" advisory statement, they cannot be declared by naming the allergen in the "Contains" statement or ingredient list, as these are reserved for declaring actual ingredients

Your Petition asks FDA to "clarify in guidance that while cross-contact risks can be declared voluntarily in a 'may contains' advisory statement, they cannot be declared by naming the allergen in the 'Contains' statement or ingredient list, as these are reserved for declaring actual ingredients" (Petition at page 3). Your Petition states that the practice of using "Contains" statements and ingredient declarations cannot be used as a form of allergen advisory statements,[2] as "this practice is clearly prohibited under [section 403(a)(1) of the FD&C Act], which states that a food is misbranded if it is 'false or misleading in any particular.' Declaring an ingredient or allergen on the ingredients list when it has not been intentionally added to a food is false or misleading and renders the food misbranded" (Id. at page 12). Your Petition "recommend[s] that the FDA clarify that this practice is prohibited in its Allergen Questions and Answers [guidance] in order to resolve any potential for confusion" (Id.).

If used, allergen advisory statements must be truthful and not misleading (see section 403(a)(1) of the FD&C Act). Recently, we have addressed the practice of using allergen advisory statements, such as "may contains [allergen]," in various guidance documents. For example, in a

[2] Allergen advisory statements are often referred to as "precautionary allergen labeling" or PAL outside of FDA.

final guidance entitled "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Final Guidance for Industry," we address the use of allergen advisory statements, noting that allergen advisory statements, such as "may contain [allergen]," are not a substitute for adherence to current good manufacturing practices or, when applicable, food allergen preventive controls. In addition, we state that any allergen advisory statement such as "may contain [allergen]" must be truthful and not misleading (see section 403(a)(1) of the FD&C Act).

In the current draft of the "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Draft Guidance for Industry," which was announced in the same *Federal Register* notice (87 FR 73561), we also state that allergen advisory statements cannot be used in lieu of good manufacturing practices and preventive controls.

In the *Federal Register* of May 17, 2023 (88 FR 31507), we announced the availability of a draft compliance policy guide (CPG) entitled "Compliance Policy Guide Sec. 555.250 Major Food Allergen Labeling and Cross-contact." In this draft CPG, we address the use of "Contains" statements directly and state, "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" and "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." We note that CSPI filed a comment to this draft CPG and that we are currently reviewing all comments timely submitted before we begin work on the final guidance. We highlight that stakeholders can comment on this CPG at any time by visiting Docket No. FDA-2023-D-1103 on www.regulations.gov.

For these reasons, we grant this request and have addressed it in the guidances noted above. Our laws and regulations do not permit the addition of "sesame," or any other major food allergen, on the label in the ingredient list or the "Contains" statement if that major food allergen is not an ingredient used to make the food. We intend to continue looking for additional opportunities to clarify that a major food allergen unintentionally present in a food due to cross-contact are not to be declared by naming the allergen in in the ingredient list or in a "Contains" statement.

III. Conclusion

For the reasons set forth above and in accordance with 21 CFR 10.30(e)(3), we: (1) deny the request to issue a notice to manufacturers declaring that companies cannot meet their obligation to control allergen cross-contact risks by adding major food allergens intentionally to foods; (2) deny the request to finalize the "Draft Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling (Edition 5)" to likewise reflect the policy that companies cannot add major food allergens to mitigate cross-contact risks; and (3) grant the request to clarify in guidance, which we have done and will look for additional opportunities to do, that allergen cross-contact risks cannot be addressed by naming the allergen in the ingredient list or the "Contains" statement, if they are not added as an ingredient.

Although FDA is not taking some of the specific actions requested in your Petition, we are actively looking into and engaging on this practice of companies intentionally adding sesame to foods that, prior to the passage of the FASTER Act, did not contain sesame.

Sincerely yours,

Claudine J. Kavanaugh -S

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