

## MEMORANDUM

**From:** Joseph A. Levitt  
Samantha Dietle

**Date:** November 6, 2018

**Re:** **FDA Issues Request for Information Regarding Sesame as an Allergen in Foods**

The U.S. Food and Drug Administration (FDA) recently issued a request for information seeking data and other information on the prevalence and severity of sesame allergies in the U.S. and the prevalence of sesame-containing foods in the marketplace that are not currently required to disclose the presence of sesame.<sup>1</sup> FDA is collecting this data to inform potential rulemaking that could require food labels to disclose the presence of sesame as an allergen in order to protect and promote public health. In addition, FDA will use this data to respond to a Citizen Petition submitted by the Center for Science in the Public Interest (CSPI) requesting that FDA issue a regulation to require sesame to be labeled as an allergen in the same manner as the eight major food allergens under the Food Allergen Labeling and Consumer Protection Act (FALCPA).<sup>2</sup>

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by FALCPA, requires food labels to disclose the presence of eight “major food allergens.” Sesame is not currently included as a “major food allergen” in the FFDCA. FDA Commissioner Scott Gottlieb explained in a blog post that at the time of passage of FALCPA, the eight major food allergies represented over 90% of serious food allergic reactions occurring in the U.S.<sup>3</sup> However, since the passage of FALCPA, FDA has become aware of additional data suggesting sesame allergies may be more prevalent than previously thought, possibly as prevalent as allergies to soy and fish – both of which are major food allergens requiring labeling. Currently, the presence of sesame may not be declared directly on food labels, as sesame may be declared collectively in the ingredient statement on a food label, such as a “natural flavor” or “spice,” or present in a form that does not disclose the presence of sesame, such as “tahini.” FDA is seeking data and information on several specific questions related to the prevalence and severity of sesame allergies in the U.S., as well as the prevalence of foods in the marketplace that do not disclose the presence of sesame in the food, in order to inform the agency’s potential rulemaking with respect to allergen labeling for sesame.

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<sup>1</sup> See Sesame as an Allergen in Foods, 83 Fed. Reg. 54594 (Oct. 30, 2018).

<sup>2</sup> The CSPI citizen petition is *available at* <https://cspinet.org/sites/default/files/attachment/11-18-sesame-petition.pdf>.

<sup>3</sup> See Statement from FDA Commissioner Scott Gottlieb, M.D., on the FDA’s new consideration of labeling for sesame allergies, October 29, 2018, *available at* <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624484.htm>.

FDA has posed the following questions in the request for information:

**A. Prevalence of Allergies and Allergic Reactions Due to Sesame in the United States**

1. What is the prevalence of IgE-mediated sesame food allergies in the United States? Please provide any studies or data that support your conclusion, and provide your unit of measure (e.g., “1 in 10,000 adults”). What is the nature of the allergic response(s) to sesame in food and what are the impacts on consumers?
2. How does the prevalence of IgE-mediated sesame food allergies in the United States compare to the prevalence of IgE-mediated allergies to the major food allergens? Please provide any studies or data that support your conclusion.
3. What proportion of allergic reactions in the United States may be attributed specifically to exposure to undeclared sesame? Please provide any studies or data that support your conclusion.
4. What proportion of allergic reactions to undeclared sesame occur in response to sesame found in packaged food products versus sesame found in foods served at retail or food service establishments (e.g., restaurants, grocery stores, supermarkets, hospitals, nursing homes, childcare centers, and temporary food establishments)?
5. In packaged food products, what proportion of allergic reactions to sesame is due to:
  - a. Sesame in generically listed spices, flavorings, colorings, or incidental additives;
  - b. Sesame used as an ingredient and listed by some other name (e.g., “tahini” rather than “sesame”); or
  - c. Cross-contact?

**B. Prevalence and Amounts of Undeclared Sesame in Foods**

1. What are examples of products or product categories that contain sesame as a spice, flavor, color, or incidental additive and that do not list “sesame” on the product labeling?
2. What amount or concentration of sesame is in products or product categories that contain sesame as a spice, flavor, color, or incidental additive and that do not list “sesame” on the product labeling? Please provide a unit of measure (e.g., “5 grams of sesame per kilogram of packaged food product” or “50 milligrams of sesame protein per serving”).
3. What are examples of products or product categories other than “spices” that contain sesame in one of the listed ingredients, but the common or usual name of that ingredient does not list “sesame,” specifically, on the product labeling? Please provide a copy of the labeling, if available.
4. What amount or concentration of sesame is in products or product categories that contain sesame in one of the listed ingredients, but the common or usual name of that ingredient does not list “sesame,” specifically, on the product labeling? Please provide a unit of

measure (e.g., “5 grams of sesame per kilogram of packaged food product” or “50 milligrams of sesame protein per serving”).

5. What are examples of food products or product categories in which sesame has been found in a product because of cross-contact?
6. What amount or concentration of sesame has been found in products or product categories that contain sesame because of cross-contact? Please provide a unit of measure (e.g., “5 grams of sesame per kilogram of packaged food product” or “50 milligrams of sesame protein per serving”).

**C. Possible Costs of Any Future Regulatory Action FDA Might Take Regarding Sesame**

1. What would the costs be if we established disclosure requirements for sesame? We are interested in any costs, specifically those to manufacturers for labeling changes to reflect sesame as an ingredient, spice, flavor, color, or incidental additive.
2. What would the costs be to manufacturers to control allergen cross-contact from sesame and what would the costs be of educating food managers at retail or food establishments to control for sesame as an allergen?
3. What steps have manufacturers taken to eliminate or reduce cross- contact from sesame and/or sesame- containing ingredients?

Comments are due to the docket on December 31, 2018.

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We will continue to monitor FDA’s rulemaking plans regarding labeling of sesame as a food allergen. Please contact us if you have any questions or if you are interested in submitting information to the docket.