

Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christopher Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6461, Silver Spring, MD 20993-0002, 301-796-0017, Christopher.Leptak@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3011 of the 21st Century Cures Act established section 507 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 357), which mandates that FDA publish a list of surrogate endpoints used as a basis to approve or license a drug or biological product under both accelerated and traditional approval provisions. The SE table fulfills this legislative requirement and is intended to provide valuable information for drug developers on endpoints that may be considered and discussed with FDA for individual development programs. FDA refers the public to the following web page for additional background information as well as the SE table: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm606684.htm>.

Section 507(e)(9) of the FD&C Act defines the term “surrogate endpoint” to mean a marker, e.g., a laboratory measurement, radiographic image,

physical sign, or other measure, that does not directly measure clinical benefit but (1) is known to predict clinical benefit and can potentially be used to support traditional approval of a drug or biological product or (2) is reasonably likely to predict clinical benefit and could be used to support accelerated approval in accordance with section 506(c) of the FD&C Act (21 U.S.C. 356(c)).

This SE table includes SEs that sponsors have used as primary efficacy clinical trial endpoints for approval of new drug applications (NDAs) or biologics license applications (BLAs). The table also includes SEs that may be appropriate for use as a primary efficacy clinical trial endpoint for drug or biologic approval, although the SEs have not necessarily been used to support an approved NDA or BLA. FDA believes that this table should facilitate discussions of potential SEs by sponsors when developers are designing their drug development programs.

II. Additional Issues for Consideration

To help FDA determine the utility of the SE table, develop future iterations of the SE table, and identify best methods for conveying this information on FDA’s website, FDA is soliciting public suggestions and comments on the SE table listed on the following web page: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm606684.htm>.

Specifically, FDA welcomes comments concerning: (1) The utility of the SE table; (2) suggestions on SEs that may not be reflected on the current SE table but that have been used for drug or biologic approvals; (3) the best approach for developing future iterations of the table, and (4) SE table questions you would like FDA to address in future communications. As required by section 507(c)(1) of the FD&C Act, FDA will update this table on the website every 6 months. The Agency will consider comments submitted to the docket as it revises the SE table.

Dated: October 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3809]

Sesame as an Allergen in Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) invites data and other information on the prevalence and severity of sesame allergies in the United States and the prevalence of sesame-containing foods sold in the United States that are not required to disclose sesame as an ingredient. We are taking this action to inform possible regulatory action on sesame to protect and promote the public health.

DATES: Submit either electronic or written comments on this document by December 31, 2018.

ADDRESSES: You may submit comments as follows. Electronic comments must be submitted on or before December 31, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 31, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-N-3809 for “Sesame as an Allergen in Foods.”

Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carol D’Lima, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2033.

SUPPLEMENTARY INFORMATION:

I. Background

Food allergies occur when the body’s immune system reacts to certain food proteins (Ref. 1). Allergic reactions to food due to immunoglobulin E (IgE) antibodies cause the body to release inflammatory chemicals and can be particularly severe, leading to symptoms such as hives, facial swelling, vomiting, wheezing, shock, and even death. Because there is no cure for food allergies, allergic consumers must use avoidance to prevent allergic reactions. Successful avoidance requires, among other things, that allergic consumers and their caregivers can read and understand the relevant information on packaged food labels and can identify food allergens in other settings, such as at retail or food service establishments.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that a food (other than a raw agricultural commodity) that bears or contains a “major food allergen” declare the allergen using its “common or usual name.” A food is misbranded if it contains a major food allergen and fails to declare that major food allergen on its label using the major food allergen’s common or usual name (section 403(w) of the FD&C Act). The FD&C Act defines a “major food allergen,” in part, as any of the following:

- Milk,
- Eggs,
- 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, and
- Soybeans.

See section 201(qq)(1) of the FD&C Act (21 U.S.C. 321(qq)(1)). When Congress amended the FD&C Act regarding food allergens in 2004, these eight foods and food groups, out of more than 160 identified food allergens, accounted for 90 percent of serious food

allergic reactions. We issued guidance in 2006 to help the public understand our implementation of the amendments, including what foods and manufacturers are subject to the amendments and labeling requirements (Ref. 2). We issued another guidance in 2014 to clarify the information we need when considering whether to exempt certain ingredients derived from major food allergens from the allergen labeling requirements (Ref. 3). These statutory requirements with respect to a label or labeling for major food allergens do not alter the authority of the Secretary of Health and Human Services under the FD&C Act to require a label or labeling for other food allergens (21 U.S.C. 343 note).

A common or usual name must accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients and can either be the name established by common use or the name required by a regulation (21 CFR 102.5). In addition to the specific requirement for allergen labeling, any food is misbranded unless its label uses: (1) The common or usual name of the food, if it has one, and (2) 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). Thus, the FD&C Act includes other authorities that assist consumers with a food allergy or other reason for avoiding an ingredient. For example, the label of a food made with sugar must declare this ingredient by its common or usual name—“sugar”—rather than the chemical name “sucrose” (see section 403(i) of the FD&C Act (21 U.S.C. 343(i))).

In addition, section 403(x) of the FD&C Act gives us the authority to issue regulations requiring the disclosure of spices, flavorings, colorings, and incidental additives that are, or contain, allergens other than the eight major food allergens. We relied on this authority, in part, to require the labeling of carmine and cochineal in foods (see 74 FR 207).

In 2014, the Center for Science in the Public Interest, several medical professionals, and two consumer advocacy groups submitted a citizen petition (Ref. 4) requesting, in part, that we issue a rule to require that sesame seeds and sesame products be regulated in a manner similar to the manner in which major food allergens are regulated under the FD&C Act, and specifically to require sesame’s disclosure by the common or usual name “sesame” in food labeling. The petition noted, among other things, that the European Union, Canada, Australia, and New Zealand require labeling of

sesame and provided scientific information to support the petitioners' argument that sesame is an allergen of public health concern. The petition also requested that we add sesame to our list of allergens in our Compliance Policy Guide, which includes discussion of adulteration due to insufficient controls to prevent potential allergen cross-contact (the unintentional incorporation of allergens into foods that are not intended to include those allergens) (Ref. 5). Since the citizen petition was posted, more than 750 comments have been submitted to the docket.

We are interested in learning more about the prevalence and severity of sesame allergies in the United States, and the prevalence of sesame-containing foods sold in the United States that are not required to disclose sesame as an ingredient. We will consider the data and other information submitted, along with previously submitted information, to inform possible steps on sesame as an allergen in food to protect and promote the public health.

II. Additional Issues for Consideration; Request for Data and Information

We invite comment, particularly scientific data and other evidence, about the following topics:

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?

III. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA. "Food Allergies: What You Need to Know." March 2017. Available at <https://www.fda.gov/downloads/Food/ResourcesForYou/Consumers/UCM220117.pdf>.
2. "Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004" (Edition 4). October 2006. Available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm059116.htm>.
3. "Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications." May 2014. Available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm395494.htm>.
4. Docket No. FDA-2014-P-2035, available at <https://www.regulations.gov/docket?D=FDA-2014-P-2035>.
5. "Compliance Policy Guide Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens." August 2000. Available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/webcontent/ucm074552.pdf>.

Dated: October 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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