Dated: October 30, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 2, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–25024 Filed 11–6–20; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0530]

Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Voluntary Disclosure of Sesame as an Allergen.'' The draft guidance, when finalized, will provide food manufacturers with FDA's current views on sesame as an allergen and will provide recommendations to voluntarily disclose sesame in certain circumstances where such disclosure is not currently required. The guidance is intended to help individuals who are allergic to sesame identify those foods that may contain sesame as an ingredient. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by January 11, 2021 to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by January 11, 2021.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2020–D–0530 for ''Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry.'' Received comments 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Nutrition and Food Labeling, Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: *With regard to the draft guidance:* Carol D'lima, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Voluntary Disclosure of Sesame as an Allergen.'' We are issuing this draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA 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 alternate approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of October 30, 2018 (83 FR 54594), we published a document inviting 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. The document also asked specific questions regarding the prevalence of allergies and allergic reactions due to sesame in the United States and the prevalence and amounts of undeclared sesame in foods. For example, we asked for examples of products or product categories that contain sesame as a spice, flavor, color, or incidental additive. The notice also stated that we had received a citizen petition in 2014 requesting, in part, that we issue a rule to require that sesame seeds and sesame products be regulated similarly to how major food allergens are regulated under the Federal Food, Drug, and Cosmetic Act (FD&C Act) (available at *https://www.regulations.gov/docket?D=FDA-2014-P-2035*). Among the various issues, the petition wanted FDA to require sesame's disclosure by the common or usual name ''sesame'' in food labeling and when present in ingredients, including a spice, flavoring, coloring, or incidental additive.

We received over 4,800 comments to the document from individual consumers and patients, as well as consumer and patient advocacy groups, medical professionals and patient caretakers, industry and trade associations, and academic institutions. Some comments submitted data and information from published studies. Data and information received in response to the document highlighted U.S. national prevalence data on sesame and other food allergens. Our communications about the notice directed the public to submit adverse events due to sesame to the CFSAN Adverse Event Reporting System (CAERS). We received over 500 individual adverse event reports.

Under our statute and regulations, if whole sesame seeds are used as an ingredient, they must be declared on the label (see section 403(i) of the FD&C Act (21 U.S.C 343(i)); 21 CFR 101.4); however, under current regulations, sesame can, in some circumstances, such as when ground in a spice blend, be declared in an ingredient statement as simply ''spice'' or ''flavor,'' so its presence may not be obvious to consumers. Some comments to the document highlighted the lack of consistent labeling of sesame on food and stated this was a major problem for those with a sesame allergy.

Based on information received in the comments to the notice, the 2014 citizen petition, and comments submitted to the corresponding docket, other correspondence, as well as adverse event reports and recent publications with prevalence data, it appears that sesame allergy may be an increasing problem in the U.S. population. We continue to evaluate the emerging evidence and are working to develop factors to inform future regulatory actions related to sesame and other emerging food allergens, including possible labeling requirements. As we engage in this important work, we recommend, in the interim, that manufacturers voluntarily take steps to help consumers who are allergic or sensitive to sesame by disclosing the presence of sesame in packaged foods, even in circumstances where such disclosure would not be required (*e.g.,* in spices and flavorings). The guidance would recommend, when finalized, that manufacturers voluntarily declare sesame in the ingredient list when it is used in foods as a ''flavor'' or ''spice'' in a parenthetical following the spice or flavor, such as, ''spice (sesame),'' ''spices (including sesame),'' ''flavor (sesame),'' or ''flavors (including sesame).'' Similarly, if a term is used for a food that is or contains sesame, such as tahini, the guidance would recommend that sesame be included in a parenthesis, *e.g.,* ''tahini (sesame)'' in the ingredient list. This will help consumers, especially those allergic to sesame, avoid foods that could cause an allergic reaction.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry

OMB Control Number 0910–0792—Revision

The draft guidance, when finalized, will provide food manufacturers with recommendations regarding voluntarily declaring sesame in certain circumstances where such declaration is not currently required. For example, if a term is used for a food that is or contains sesame, the guidance would recommend that sesame should be included in a parenthesis in the ingredient list.

Description of respondents: The respondents to this collection of information are manufacturers and packers of packaged foods sold in the United States.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs
Review labels to follow guidance recommendations	77,500	1	77,500	1	77,500	0
Redesign labels to follow guidance recommendations	775	1	775	16	12,400	$1,414,375
Total					89,900	1,414,375

[1] There are no operating and maintenance costs associated with this collection of information.

We base these estimates from our experience with our food allergen labeling program and our labeling cost model. We estimate that there are approximately 775,000 Universal Product Codes (UPCs) of FDA-regulated foods. Using FDA's labeling cost model, we estimate the entry rate of new UPCs to be approximately 8 percent per year. Based on the approximate entry rate of new UPCs, we estimate the rate of new or reformulated UPCs to be approximately 10 percent per year, or 77,500 products (775,000 ×10 percent). Thus, we estimate that 77,500 new or reformulated products are sold annually in the United States. Assuming an association of 1 respondent to each of the 77,500 new or reformulated products, we estimate that 77,500 respondents will each review the label of one of the 77,500 new or reformulated products, as reported in table 1, row 1. We have no data on how many label reviews would identify an opportunity to redesign the label. Therefore, we further estimate, for the purposes of this analysis, that 1 percent of the reviewed labels of new or reformulated products, or 775 labels (77,500 × 1 percent) would be redesigned as recommended by the guidance. Assuming an association of 1 respondent to each of the 775 labels, we estimate that 775 respondents will each redesign 1 label. Using our labeling cost model, we estimate that it will take an average of 16 hours to complete the administration and internal design work for the redesign of a label to follow the recommendations of the guidance, as reported in table 1, row 2. Consequently, the burden of redesigning the 775 labels of new or reformulated products is 12,400 hours, as reported in table 1, row 2.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: November 2, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–24727 Filed 11–10–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–N–3065; FDA–2016–N–4620; FDA–2019–N–6063; FDA–2017–N–1066; FDA–2018–N–3065; FDA–2008–N–0424; and FDA–2019–N–5711]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Required Warnings for Cigarette Packages and Advertisements	0910–0877	04/30/2023
Medical Devices; Reports of Corrections and Removals	0910–0359	10/31/2023
Customer/Partner Service Surveys	0910–0360	10/31/2023
Annual Reporting for Custom Device Exemption	0910–0767	10/31/2023
Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act	0910–0800	10/31/2023
Postmarketing Safety Reporting for Combination Products	0910–0834	10/31/2023
Importation of Prescription Drugs	0910–0888	10/31/2023