DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4849]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Allergen Labeling and Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with statutory provisions applicable to ingredients derived from major food allergens.

DATES: Either electronic or written comments on the collection of information must be submitted by February 6, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 6, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2023–N–4849 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food Allergen Labeling and Reporting.'' 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, 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.'' The Agency will review this copy, including the claimed confidential information, in its 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.

FOR FURTHER INFORMATION CONTACT: 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: Under the 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, including each proposed extension of an existing 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 the following 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.

Food Allergen Labeling and Reporting

OMB Control Number 0910–0792—Revision

This information collection helps support implementation of statutory requirements pertaining to ingredients derived from major food allergens. The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines the term ''major food allergen'' (section 201(qq) of the FD&C Act (21 U.S.C. 321(qq))) and provides that foods are misbranded unless they declare the presence of each major food allergen on the product label using the name of the food source from which the major food allergen is derived or are exempt from the requirement. Under sections 403(w)(6) and (7) of the FD&C Act (21 U.S.C. 343(w)(6) and (7)), respondents may request an FDA determination that an ingredient is exempt from the labeling requirement of section 403(w)(1) of the FD&C Act. Alternatively, an ingredient may become exempt through submission of a notification containing scientific evidence showing that the ingredient ''does not contain allergenic protein'' or that there has been a previous determination through a premarket approval process under section 409 of the FD&C Act (21 U.S.C. 348) that the ingredient ''does not cause an allergic response that poses a risk to human health'' (section 403(w)(7) of the FD&C Act).

To assist respondents with the information collection in this regard, the document entitled ''Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications'' (June 2015), available on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-allergen-labeling-exemption-petitions-and-notifications,* communicates information we recommend respondents include in petitions submitted under sections 403(w)(6) and (7) of the FD&C Act or notifications submitted under section 409 of the FD&C Act. We use the information submitted in the petition or notification to determine whether the ingredient satisfies the criteria of section 403(w)(6) and (7) of the FD&C Act for granting the exemption. The allergen information disclosed on the label or labeling of a food product benefits consumers who purchase that food product. Because even small exposure to a food allergen can potentially cause an adverse reaction, consumers rely upon food labeling information to help determine their product choices.

On April 23, 2021, the definition of the term *major food allergen* was amended by the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act) (Pub. L. 117–11) to include sesame. Accordingly, we are revising the information collection to account for burden attributable to required declarations and/or associated requests for exemption as they pertain to foods that include sesame. We issued the draft guidance document entitled ''Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5)'' (November 2022), available on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5,* that once finalized, will communicate our current thinking regarding the labeling of food allergens, including sesame in food products regulated under section 403 of the FD&C Act. The guidance was issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Description of Respondents: The respondents to this collection of information are manufacturers and packers of packaged foods sold in the United States subject to the labeling requirements and prohibitions found in section 403 of the FD&C Act.

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

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

FD&C Act Section; information collection activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs
403; review product labeling for compliance with applicable statutory requirements	77,500	1	77,500	1	77,500	0
403; redesign/modifications to product labeling for compliance with applicable statutory requirements	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.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act Section; information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
403(w)(6); petition for exemptions	6	1	6	100	600
403(w)(7); notification submissions	6	1	6	68	408
Total					1,008

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

Our estimate of the third-party disclosure burden associated with food allergen labeling under section 403(w)(1) of the FD&C Act includes the time we assume respondents need to review the labels of new or reformulated

products for compliance with the requirements of section 403(w)(1) of the FD&C Act, along with the time needed to make any needed modifications to the labels of those products. We believe firms have already redesigned their labels to comply with requirements under the Food Allergen Labeling and Consumer Protection Act of 2004. However, this estimate accounts for firms that will redesign their label to comply with requirements under the FASTER Act. Our estimated reporting burden is based on our past experience with these submissions. We have increased our cumulative estimate by 12,552 hours and 776 responses annually to reflect the inclusion of sesame as a major food allergen.

Dated: December 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2851]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Time and Extent Applications for Nonprescription Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 8, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0688. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Time and Extent Applications for Nonprescription Drug Products

OMB Control Number 0910–0688—Revision

I. Background

This information collection supports certain Agency regulations in part 330 (21 CFR part 330) regarding over-the-counter (OTC) human drugs and associated guidance. Specifically, FDA regulations in §§ 330.14 and 330.15 (21 CFR 330.14 and 330.15) establish additional criteria and procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded. These regulations provide that OTC drug products introduced into the U.S. market after the OTC drug review began in 1972 and OTC drug products without any marketing experience in the United States can be evaluated under the OTC monograph system if the conditions (*e.g.,* active ingredients) meet certain ''time and extent'' criteria outlined in the regulations. The regulations in § 330.14 allow a sponsor to submit certain information to the Agency in a time and extent application (TEA) for use to determine eligibility of a condition for consideration in the OTC monograph system.

We developed the final guidance document entitled ''Time and Extent Applications for Nonprescription Drug Products'' (September 2011) (available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/time-and-extent-applications-nonprescription-drug-products*) to assist respondents with the information collection provisions found in the regulations. The guidance was issued consistent with our good guidance practice regulations at 21 CFR 10.115, which provide for comment at any time. The guidance explains what information an applicant should submit to the Agency to request that a drug product be included in the OTC drug monograph system. The guidance also discusses format and content elements, and the process for submitting information, consistent with the applicable regulations.

II. OTC Monograph Reform in the Coronavirus Aid, Relief, and Economic Security Act

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act (Pub. L. 116–136, Stat. 281)) signed March 27, 2020, included provisions that govern the way certain OTC drugs are regulated in the United States. The CARES Act added section 505G to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h), which reforms and modernizes the OTC drug review process, including establishing new procedures for consideration of additions or changes to conditions covered in OTC monographs. As a result of these revised statutory provisions, we anticipate no submissions under § 330.14. Our OTC *Monographs@FDA* portal (*https://dps.fda.gov/omuf*) provides additional information about OTC monograph drugs and the OTC drug review process.

Consistent with section 505G(k)(3) of the FD&C Act, we plan to withdraw the regulations supporting the TEA provisions in part 330 and discontinue the related guidance document. When these actions occur, we will also request discontinuation of the information collection approved under OMB control number 0910–0688.

In the **Federal Register** of August 8, 2023 (88 FR 53497), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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