website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: April 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07657 Filed 4–10–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4849]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Allergen Labeling and Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 May 13, 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 0910–0792. Also include the FDA docket number found in brackets in the heading of this document.

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

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.

In the **Federal Register** of December 8, 2023 (88 FR 85640), we published a 60-day notice soliciting comment on the proposed collection of information. Although one comment was received, we believe it was misdirected. The comment pertained to neither the topic of this notice, nor the four information collection topics solicited.

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: April 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Draft Health Center Program Policy Guidance Regarding Services To Support Transitions in Care for Justice-Involved Individuals Reentering the Community

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for public comment on draft Health Center Program policy guidance regarding services to support transitions in care for Justice-involved individuals reentering the community.

SUMMARY: HRSA is inviting public comment on the draft Health Center Program Policy Guidance Regarding Services to Support Transitions in Care for Justice-Involved Individuals Reentering the Community. The purpose of the draft Policy Information Notice (PIN) is to propose Health Center Program policy guidance for all health centers that apply for and receive federal award funds under the Health Center Program, as authorized by section 330 of the Public Health Service (PHS) Act (including sections 330(e), (g), (h), and (i)), as well as section 330 subrecipient organizations and Health Center Program look-alikes, to clarify the conditions under which they may provide certain health services as part of the Health Center Program scope of project to certain incarcerated/detained individuals. This draft PIN establishes policy guidance that identifies a set of health services that a health center may provide, the locations at which such services may be provided, the target population for such services (specifically, incarcerated/detained individuals who are scheduled for release from a carceral setting within 90 days), and other pertinent circumstances under which the health center may, on its own behalf and subject to all section 330 requirements, provide such services to justice-involved individuals reentering the community to support their care transition from the carceral setting to the community within the scope of their Health Center Program project.

DATES: Submit comments on or before June 14, 2024.

ADDRESSES: Electronic comments should be submitted through the HRSA Bureau of Primary Health Care Contact Form (*https://hrsa.my.site.com/support/s/*), ''Comment on Draft Policy'' under the ''Policy'' section. Comments should be submitted no later than 60 days after the publication date.

FOR FURTHER INFORMATION CONTACT: Jennifer Joseph, Office of Policy and Program Development Director, HRSA, at *jjoseph@hrsa.gov* and 301–594–4300.

SUPPLEMENTARY INFORMATION: HRSA provides grants to eligible applicants under section 330 of the PHS Act, as amended (42 U.S.C. 254b), to support the delivery of preventive and primary