TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section and activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response (in hours)	Total hours
§ 1107.1(b) Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request Including § 25.40 Preparation of an Environmental Assessment					
§ 1107.1(b)—Preparation of tobacco product exemption from substantial equivalence request and § 25.40—Preparation of an environmental assessment	682	1	682	24	16,368
Total Hours (§ 1107.1(b))					16,368
§ 1107.1(c) Preparation of Additional Information for Tobacco Product Exemption From Substantial Equivalence Request					
§ 1107.1(c)—Preparation of additional information for tobacco product exemption from substantial equivalence request	150	1	150	3	450
Total Hours (§ 1107.1(c))					450
Section 905(j)(1)(A)(ii) of the FD&C Act: If exemption granted, report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)					
Abbreviated report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant, and modifications covered by exemptions granted by Secretary under section 905(j)(3)	186	1	186	2	372
Total Hours (section 905(j)(1)(A)(ii)) of the FD&C Act					372
Total Hours Exemptions From Substantial Equivalence Requirements					17,190

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

FDA estimates that we will receive 682 exemption requests under § 1107.1(b) for 24 hours per response including EA for a total of 16,368 hours. We have reduced the number of respondents from 812 to 682 based on the average number of applications received during the past 3 fiscal years. Since an EA is required for each § 1107.1(b) (Optional Preparation of Tobacco Product Exemption From Substantial Equivalence Request), the burden per response for EAs (12 hours) has been combined with the 12 hours for a substantial equivalence request for a total of 24 hours per response.

FDA further estimates that we will receive 150 submissions requiring additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information for a total of 450 hours.

FDA estimates that 186 respondents will prepare 186 responses and each response will take approximately 2 hours to prepare, as required by section 905(j)(1)(A)(ii) of the FD&C Act, for a total of 372 hours. We have reduced the number of respondents as required by section 905(j)(1)(A)(ii) (abbreviated reports) from 1,217 to 186 based on the average authorizations issued during the past 3 fiscal years. This collection of information requires a manufacturer to submit a report at least 90 days prior to making an introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product. Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, the manufacturer must submit to FDA a report that demonstrates that the tobacco product is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the FD&C Act, and all the modifications are covered by exemptions granted by the Secretary under section 905(j)(3).

Our estimated burden for the information collection reflects an overall decrease of 5,182 hours and 1,161 respondents. We attribute this adjustment to the number of submissions we received over the past few years. Therefore, FDA now estimates the burden for exemptions from substantial equivalence requirements is 17,190 hours.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11950 Filed 6–26–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5579]

Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and Issue Certifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 requirements for the accreditation of third-party certification bodies to conduct food safety audits and issue certifications.

DATES: Either electronic or written comments on the collection of information must be submitted by August 26, 2025.

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 August 26, 2025. 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–2024–N–5579 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications.'' 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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 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.

Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and Issue Certifications—21 CFR Part 1, Subpart M

OMB Control Number 0910–0750—Extension

This information collection supports FDA's Accredited Third-Party Certification Program (also referred to as the third-party food program or TPP), administered under section 808 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384d), and codified in 21 CFR part 1, subpart M (21

CFR 1.600 through 1.725) of Agency regulations. The regulation communicates eligibility criteria, assessment standards, and establishes procedures and requirements for participation. For more information visit our website at *https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program.*

Under TPP, accreditation bodies (ABs) apply to FDA for recognition. Recognized ABs accredit third-party certification bodies (CBs) under the program, except in limited circumstances. The accredited CBs conduct food safety audits and issue food or facility certifications to eligible foreign entities. Section 808(c)(2)(B) of the FD&C Act specifies that FDA uses certifications issued by accredited CBs under TPP in deciding whether to admit certain imported food (both food for human and food for animals) into the United States that we have determined poses a food safety risk under section 801(q) of the FD&C Act (21 U.S.C. 381(q)) and in deciding whether an importer is eligible to participate in a program for expedited review and entry under section 806 of the FD&C Act (21 U.S.C. 384b). Under TPP, FDA may grant recognition of an AB for up to 5 years from the date of recognition. There are current AB participants that are recognized through fiscal year 2027 or 2028 and will need to submit renewal of recognition applications to continue their participation. Specific requirements and procedures are found in 21 CFR part 1, subpart M.

There are approximately 200,000 foreign food (both food for human and food for animals) exporters who offer their food products for import into the United States. These foreign food exporters include approximately 130,000 food production facilities and approximately 71,000 farms. A proportion of these foreign food exporters may offer food subject to mandatory certification requirements under section 801(q)(3) of the FD&C Act. In that case, to continue importing food products into the United States, eligible entities must either obtain certification from a CB accredited under TPP, or obtain certification from a foreign government designated by FDA. We assume in any given year, 75 foreign food exporters will be subject to requirements in section 801(q) of the FD&C Act.

Use of accredited CBs and food and facility certifications issued under TPP helps reduce the number of redundant audits necessary to assess compliance with food safety requirements of the FD&C Act and applicable regulations. We have developed Forms FDA 3997 and FDA 3997a to enable respondents to submit required data elements using FDA's Unified Registration Listing System (FURLS), an electronic portal (Forms FDA 3997 for ABs and 3997a for CBs) that enables respondents to complete data fields and provide information to FDA electronically. The AB and CB portals provide a standardized format for entering information, prompting respondents for input, and facilitating FDA's review of the submittal. Respondents are subject to user fees for application, renewal, and annual fees, as set forth in 21 CFR 1.700 through 1.725. The user fee rates are calculated each fiscal year and published in the **Federal Register** before the start of a new fiscal year. Electronic portal instructions and user fee information may be accessed at *https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program.*

Respondents to the collection of information are the accredited CBs that conduct audits and issue certifications to eligible entities, the ABs and CBs seeking to participate in TPP, and the recognized ABs and accredited CBs complying with the TPP requirements. An accredited CB is a foreign government, agency of a foreign government, foreign cooperative, or any other third party that a recognized AB (or, in the case of direct accreditation, FDA) has determined meets the applicable requirements of TPP and is accredited to conduct food safety audits and to issue food or facility certifications to eligible entities. An AB is an authority, such as a private third-party, foreign government, or foreign agency, that performs accreditation of CBs. A recognized AB is an AB that FDA has determined meets the applicable requirements of TPP and is authorized to accredit CBs under TPP.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 1; subpart M	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response [2]	Total hours
AB applications, applications for renewals, notifications, and revocations.	25	11.36	284	3.18	903
CB certifications, regulatory audits and assessments, notifications.	208	147.30	30,638	0.25 (15 minutes)	7,660
CB applications for direct accreditation & renewal	1	1	1	90	90
Total			30,923		8,653

[1] There are no capital costs or operating and maintenance costs associated with annual reporting.
[2] Figures rounded to nearest 1/100th as calculated based on total number of records and hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part 1; subpart M	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeping [2]	Total hours
AB documenting procedures for accreditation; maintaining applicable records.	25	426.56	10,664	0.25 (15 minutes)	2,666
AB establishing and updating public list of CBs	25	1	25	52.8	1,320
CB documenting certification procedures; maintaining applicable records (audits, certifications, serious risks).	208	113.04	23,512	0.35 (~20 minutes)	8,229
CB establishing and updating public list of eligible entities	208	1.31	273	44.19	12,064

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR part 1; subpart M	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeping [2]	Total hours
Contract modification	7	9	63	2	126
Total			34,537		24,405

[1] There are no capital or operating and maintenance costs associated with the annual recordkeeping burden.
[2] Figures rounded to the nearest 1/100th as calculated based on total number of records and hours.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11962 Filed 6–26–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5944]

Agency Information Collection Activities; Proposed Collection; Comment Request; Sanitary Transportation of Human and Animal Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 the information collection requirements associated with the sanitary transportation of human and animal food.

DATES: Either electronic or written comments on the collection of information must be submitted by August 26, 2025.

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 August 26, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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- 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'').

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- 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–2024–N–5944 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Sanitary Transportation of Human and Animal Food.'' 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