4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-5579]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 0910-0750." Also include the FDA docket number found in brackets in the heading of this document.

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

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.

In the *Federal Register* on June 27, 2025 (90 FR 27625), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Part 1; Subpart M	No. of Respondents	No. 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	No. of Recordkeepers	No. 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	272	44.19	12,020
Contract modification	7	9	63	2	126
Total			34,536		24,361

[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. However, a miscalculation in the burden estimate was identified during a review of the prior renewal and has been corrected.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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