4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0721]

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: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0750. 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-45, 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.

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 helps to implement FDA's Accredited Third-Party Certification Program (also referred to as the third-party food program), established and 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 parts 1.600 through 1.725) of Agency regulations. The regulations communicate eligibility criteria, assessment standards, and establish 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 the third-party food program, 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. FDA uses certifications issued by accredited third-party auditors/CBs in deciding whether to admit certain imported food (both food for human and other animals) into the United States. Under the third-party program, FDA may grant recognition of an AB for up to 5 years from the date of recognition. Current third-party program AB participants are recognized for the duration from 2018 to 2023 and will need to submit renewal of recognition applications to continue their participation.

There are approximately 200,000 foreign food (both food for human and other 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 (21 U.S.C. 381(q)(3)). In that case, to continue exporting food products into the United States, eligible entities must either obtain certification from a CB accredited under the third-party program, 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.

Participating in the third-party accreditation program helps reduce the number of redundant audits necessary to assess compliance with food safety requirements of the FD&C Act and applicable regulations. Required data elements are submitted 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. Instructions 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 eligible entities seeking audits, certification, and/or recertification by accredited CBs participating in the third-party program, and ABs and CBs seeking to comply with the recognition requirements. An eligible entity is a foreign entity in the import supply chain of food for consumption in the United States that chooses to be subject to a food safety audit conducted by an accredited third-party CB.

In the *Federal Register* of February 16, 2022, (87 FR 8846), we 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:

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. renewals, notifications, revocations	25	11.36	284	3.18	903

CB certifications, regulatory audits and assessments, notifications	208	147.29	30,638	0.25 (15 minutes)	7,661
CB applications for direct accreditation & renewal	1	1	1	90	90
Total			30,923		8,654

[1] We estimate no capital costs or operating and maintenance costs for the information collection.
[2] Figures rounded to the nearest one, one-hundred 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 certification procedures; maintaining applicable records	25	426.56	10,664	0.25 (~15 minutes)	2,677
AB establishing and updating public list of CBs	25	1	25	52.8	1,320
CB documenting procedures for accreditation; maintaining applicable records (audits, certifications, serious risks)	208	112.72	23,446	0.35 (~20 minutes)	8,228
CB establishing & updating public list of eligible entities	208	1.31	273	44.19	12,064
Contract modification[2]	7	9	63	2	126
Total			34,471		24,415

[1] We estimate no capital costs, or operating and maintenance costs for the information collection.
[2] Figures rounded to the nearest one, one-hundred as calculated based on total number of records and hours.

We include in our estimate reporting burden attributable to required submissions, including notifications, to FDA; and recordkeeping burden attributable to the time we assume necessary for searching data sources, and preparing and maintaining records described in the applicable regulations. We estimate that 25 ABs will accredit CBs who conduct food safety audits of foreign eligible entities that offer food for import to the United States. We also estimate the 208 accredited CBs will participate in the third-party program. In addition, we expect that one CB will apply and participate in the third-party program via direct accreditation by FDA. Finally, we attribute nominal burden to recordkeeping attendant to contractual modifications that may be part of accreditation.

Based on a review of the information collection since last OMB approval, we have made only nominal adjustments to our burden estimate.

Dated: June 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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