United States Food and Drug Administration

Accreditation of Third-Party Certification Bodies
to Conduct Food Safety Audits and Issue Certifications

OMB Control No. 0910-0750

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration's (FDA's) Accredited Third-Party Certification Program (also referred to as the third-party 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 on 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 use certifications issued by accredited CBs under TPP in deciding whether to admit certain imported food (both food for human and food for other animals) into the U.S. 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 other animals) exporters who offer their food products for import into the U.S. 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) of the FD&C Act. In that case, to continue importing food products into the U.S., 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.

We therefore request approval for the information collection provisions in 21 CFR part 1, subpart M (1.600-1.725), as well as the electronic portal (Forms FDA 3997 for ABs and 3997a for CBs), as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We use certifications issued by accredited CBs in deciding whether to admit certain imported food into the U.S. that we have determined poses a food safety risk, and in deciding whether an importer is eligible to participate in a program for expedited review and entry of food imports. Except for limited circumstances in which we may directly accredit CBs to participate in the TPP, we recognize ABs to accredit CBs. We believe that establishment of this program for foreign food safety audits and food and facility certifications help us prevent potentially harmful food from reaching U.S. consumers and thereby improves the safety of the U.S. food supply. Widespread participation and broad acceptance of audits and certifications under the program would likely help increase efficiency by eliminating redundant auditing to assess foreign suppliers' compliance with the FD&C Act and FDA regulations.

Description of Respondents: Respondents to this information collection 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. Private sector respondents to this information collection include non-profit and for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

The regulations require ABs and CBs to electronically maintain records and submit reports or notifications to FDA. We believe that currently all ABs and CBs have appropriate information technology to comply with these information collection requirements. Further, we have established an electronic portal for respondents to submit information. Therefore, we estimate that 100% of the respondents will use electronic means to fulfill the agency's requirement or request. We have also created user guides to assist respondents in this regard.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We believe this collection of information imposes no undue burden on small entities. At the same time, we assist small businesses and other respondents in complying with agency regulations through resources available from our website, along with small business contacts throughout the agency.

6. Consequences of Collecting the Information Less Frequently

The collection of information for this information collection occurs occasionally, consistent with statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of June 27, 2025 (90 FR 27625). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Privacy Act

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3997 (Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications) and Form FDA 3997a, is name, phone number, fax number, mailing address, email address, account credentials, and password. We have determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public (see 21 CFR 20), consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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

Activity under 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 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]

Activity under 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; maintaining applicable records (audits, certifications, serious risks)	208	113.04	23,512	0.35 (~ 20 minutes)	8,229
CB establishing & 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 maintenance costs associated with annual recordkeeping burden.
[2] Figures rounded to the nearest 1/100th 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 reviewing instructions, searching existing data sources, completing and reviewing each collection of information, 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 TPP, including one CB that will apply and participate in

TPP via direct accreditation by FDA. Finally, we attribute nominal burden to recordkeeping attendant to contractual modifications that may be part of recognition or accreditation.

12b. Annualized Cost Burden Estimate

We estimate the annualized burden hour cost to respondents for this collection of information to be approximately $4,513,739.32. We estimate that the required reports, annual updates, and occasional updates are prepared by an employee making an average wage similar to that of a Federal government employee at the GS-14/Step-1 rate for the Washington-Baltimore Locality Pay Area for the year 2025, which is $68.27 per hour. To account for overhead, this cost is increased by 100 percent, which is $136.54 per hour. Thus, the annual wage cost for reporting and recordkeeping is approximately $4,513,739.32 (33,058 hours x $136.54 per hour).

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, or maintenance costs associated with this information collection. Annualized operations costs associated with this information collection are determined by FY user fee assessments. As published in the *Federal Register* of July 30, 2025 (90 FR 35906), below are the current fee schedules:

Table 3.--FSMA Third-Party Certification Program User Fee Schedule for FY 2026

Fee Category	Fee Rates for FY 2026
Initial Application Fee for Accreditation Body Seeking Recognition	$53,440
Annual Fee for Recognized Accreditation Body	$2,498
Annual Fee for Accredited Certification Body	$3,122
Initial Application Fee for a Certification Body Seeking Direct Accreditation from FDA	$53,440
Renewal Application Fee for Recognized Accreditation Body	$32,724

Table 4.--Estimated Fee Rates for Other Fee Categories Under the FSMA Third-Party Certification Program

Fee Category	Estimated Fee Rates for FY 2025
Renewal Application Fee for Directly Accredited Certification Body	$32,724
Annual Fee for Certification Body Directly Accredited by FDA	$25,152

14. Annualized Cost to the Federal Government

This program is supported by user-fees, and we therefore estimate no cost to the Federal government.

15. Explanation for Program Changes or Adjustments

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.

16. Plans for Tabulation and Publication and Project Time Schedule

We have made available on our website a publicly available registry of recognized ABs and accredited CBs, including the name, link to the company website, contact information, and scope(s) and duration of recognition or accreditation.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.