UNITED STATES FOOD & 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, the agency, us or we) Accredited Third Party Certification Program. Under the FDA Food Safety and Modernization Act (FSMA), we have established an accreditation program providing for third-party certification bodies (CBs) to conduct food safety audits of eligible foreign food facilities, and issue certifications for eligible foreign food and facilities certifications, as mandated by the FDA Food Safety Modernization Act. To implement these provisions we codified regulations at 21 CFR part 1, subpart M.

Generally, an accreditation body seeking recognition must demonstrate that it has authority to perform assessments of a third-party CB so that FDA may determine its capability to conduct audits and certify food facilities and food. Certifications issued by third-party CBs are used in deciding whether to admit certain imported food into the United States 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 accredited third-party certification program, we will recognize accreditation bodies (ABs) to accredit third-party CBs. Specific requirements and procedural regulations are found in parts 1.600 through 1.695.

To assist respondents to the information collection we developed an on-line application process. Upon submitting an application or renewal application to the program, respondents are subject to user fees, as set forth in parts 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.

We therefore request extension of OMB approval for the information collection provisions in 21 CFR part 1, subpart M (1.600-1.725), as well as the online application portal (approved March 2, 2017), as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We use certifications issued by accredited third-party 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 accredited third-party certification program, we recognize ABs to accredit CBs. We believe that establishment of this program for foreign food safety audits and food and facility

certifications helps 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 helps increase efficiency by eliminating redundant auditing to assess foreign suppliers' compliance with the FD&C Act and FDA regulations.

Description of Respondents: Respondents to the collection are eligible entities seeking audits, certification, and/or recertification by accredited CBs participating in our 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 U.S. that chooses to be subject to a food safety audit conducted by an accredited third-party CB.

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.

4. Efforts to Identify Duplication and Use of Similar Information

This collection of information pertains to current regulations regarding food safety. 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 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 February 20, 2019 (84 FR 5084). A number of comments were submitted and those responsive to the information collection are discussed here:

> *Comment 1*: One comment suggested that the agency should conduct all food safety audits instead of allowing third-party entities to conduct them which would allow for greater accountability.
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> *Response*: With limited resources, the agency would be inundated with conducting food safety audits for the thousands of foreign suppliers importing products to the United States every day. With accredited third-party CBs and ABs, we can leverage their food safety activities to benefit our system of public food safety assurances. In doing so, we can prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply.
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> *Comment 2*: One comment suggested that there would be less burden for the public to deal directly with FDA instead of a 3rd party.
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> *Response*: The Accredited Third-Party Certification Program reduces burden for the public. Widespread participation and broad acceptance of audits and certifications under the program helps increase efficiency by eliminating redundant auditing to assess foreign suppliers' compliance with the FD&C Act and FDA regulations.
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> *Comment 3*: One comment offered that the Third-Party Program is a resourceful and competitive way to perform food safety audits and issue certifications.
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> *Response*: We agree with this comment. The use of accredited third-party CBs and food and facility certifications helps us prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply. This collection of information increases efficiency by reducing the number of redundant audits to assess compliance with applicable food safety requirements of the FD&C Act and FDA regulations.

With regard to the publication of user fee rates, in the Federal Register of August 30, 2018 (84 FR 44277) we published a notice announcing FY 2019 annual fee rates for recognized accreditation bodies and accredited certification bodies, and the fee rate for accreditation bodies to be recognized in the third-party certification program.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

This collection does not specify confidentiality. However, records that may be reviewed by FDA are subject to FDA regulations on the release of information found in 21 CFR part 20. Confidential commercial information is protected from disclosure under FOIA in accordance with sections 5 U.S.C. 552(a) and (b) and by 21 CFR part 20. To the extent that § 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

Privacy Act

This ICR does not request any personally identifiable information and does not include a form that requires a Privacy Act Statement.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We estimate the burden for this collection of information as follows:

Table 1 – Estimated Annual Recordkeeping Burden[1]

21 CFR part 1; subpart M	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping (in hours)	Total Hours
AB recordkeeping (1.615; 1.624; and 1.625)[2]	7	1	7	2	14
3rd Party CB recordkeeping (1.645; 1.651; 1.653; 1.656; and 1.657)	208	166.44	34,620	1.381	25,053
Contract modification[2]	7	9	63	2	126
TOTAL			34,690		25,193

[1] There are no operations and maintenance costs associated with annual recordkeeping burden.
[2] Initial burden for an AB seeking recognition or a CB seeking accreditation.

For purposes of this analysis, we assume that all ABs that apply for recognition in the program become recognized and all CBs that apply for accreditation are accredited.

Table 2 -- Estimated Annual Reporting Burden[1]

21 CFR Part 1; Subpart M	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response (in hours)	Total Hours
AB applications for recognition (1.630)	7	1	7	80	560
AB reports and notifications (1.623)	25	10	250	.248	62
Revocations – requested records (1.634)	25	1	25	8.4	210
3rd party CB reports and notifications (1.656)	208		30,587	.25	7,648
Applying for direct accreditation or renewal (1.670)[2]	1	1	1	80	80
TOTAL			30,870		8,560

1 There are no operating or maintenance costs associated with annual reporting

2 Initial burden for an AB seeking recognition or a CB seeking accreditation.

An accreditation body is eligible to seek recognition by FDA if it can demonstrate that it meets the requirements of §§1.611 through 1.615. The accreditation body may use documentation of conformance with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17011:2004, supplemented as necessary, in meeting the applicable requirements. We estimate that 25 ABs will accredit CBs that will conduct food safety audits of foreign eligible entities that offer food or feed for import to the United States. We also estimate that approximately 208 CBs accredited by the 25 AB applicants will comply with the collection of information to participate in the program. In addition, we expect that one CB will apply and participate in the third-party program via direct accreditation by FDA under this collection of information.

12b. Annualized Cost Burden Estimate

Annualized costs associated with information collection are determined by FY user fee assessments. As published in the Federal Register of November 27, 2019 (84 FR 44277), below is the current fee schedules:

FSMA Third-Party Certification Program User Fee Schedule for FY 2019

Fee Category	Fee Rates for FY 2019
Initial Application Fee for Accreditation Body Seeking Recognition	$38,211
Annual Fee for Recognized Accreditation Body	$1,775
Annual Fee for Accredited Certification Body	$2,219
Initial Application Fee for a Certification Body Seeking Direct Accreditation from FDA	$38,211

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

Fee Category	Estimated Fee Rates for FY 2019
Renewal application fee for recognized accreditation body	$21,350
Renewal application fee for directly accredited certification body	$28,999
Annual fee for certification body directly accredited by FDA	$21,056

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The program is supported by user fees.

15. Explanation for Program Changes or Adjustments

This information collection reflects adjustment where we assume burden associated with one-time recordkeeping and reporting activities generated by the new requirements have now been realized. This results in decreases of 7,421 responses and 41,069 total burden hours. We have also made adjustments to previous cost estimates, where instead we include current year's user fee rates consistent with the regulations.

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 of and contact information for such bodies. Such registry may provide information on CBs accredited by recognized ABs through links to the websites of such ABs.

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.