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

OMB Control No. 0910-0750
SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 307 of the Food Safety Modernization Act (FSMA), Accreditation of Third-Party Auditors, amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to create a new provision, section 808, under the same name (21 U.S.C. 384d). It requires the Food and Drug Administration (FDA) to establish a system, within two years of enactment, for the recognition of accreditation bodies that accredit third-party certification bodies(CB) to conduct food safety audits and to issue certifications for eligible foreign food facilities and their products (21 U.S.C. 384d(b)(1)(A)). While the statute uses the term "auditor" to describe an entity that conducts audits and issues certifications, we use the term "certification body," which better comports with the terminology used by the food industry and the international standards community. The statute further provides that if FDA has not identified and recognized an accreditation body that meets the requirements of the section within two years after establishing the system for recognition, then FDA may begin to directly accredit third-party certification bodies (21 U.S.C. 384d(b)(1)(A)(ii)). FDA direct accreditation of CBs may occur only when both conditions are met.

FSMA section 307(b)(2) also requires FDA to issue model accreditation standards that third-party certification bodies must meet in order to be qualified for accreditation under FDA's program (21 U.S.C. 384d(b)(2)). The statute specifies that the model accreditation standards must include requirements for regulatory audit reports and must look to existing standards for guidance to avoid unnecessary duplication of efforts and costs (21 U.S.C. 384d(b)(2)). Finally, the regulations must contain protections against conflicts of interest between accredited third party auditors/certification bodies (and their audit agents) and the entities they audit or certify, including requirements on timing and public disclosure of fees and appropriate limits on financial affiliations (21 U.S.C. 384d(c)(5)(C)(ii) and (iii)). And in addition, the regulations must require audits to be unannounced (21 U.S.C. 384d(c)(5)(C)(i)).

FSMA section 307 describes two types of certifications that may be issued by accredited third-party CBs: facility and food certifications. Facility certifications described in FSMA §§ 302(a) and 307(c)(2) will be used by FDA to help determine whether a facility is eligible to be a facility from which food may be offered for import under the voluntary qualified importer program (VQIP) (21 U.S.C. 384b(d)). FDA is currently developing guidance on VQIP and will solicit public comment consistent with its good guidance practices regulations found at 21 CFR 10.115.

Food certifications described in FSMA §§ 303(b) and 307(c)(2) will be used by FDA, in conjunction with any other assurances FDA may require, to help determine whether a food complies with the applicable requirements of the Act and should be admitted into the United States (U.S.) (21 U.S.C. 381(q)). FDA may require certification or other assurance of compliance to admit an imported food into the U.S., where FDA determines that such assurance is necessary based on the risk of the food.

Before an accredited third-party CB may issue either type of certification, the CB must conduct a regulatory audit and any other activities necessary to establish compliance with the requirements of §§ 801(q) or 806, respectively (21 U.S.C. 384d(c)(2)(C)(i)).

2. Purpose and Use of the Information Collection

FDA will use certifications issued by accredited third-party auditors/CBs in deciding whether to admit certain imported food into the U.S. that FDA has 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 audits and certification program, we will recognize accreditation bodies (ABs) to accredit third-party auditors/certification bodies (CBs). We believe that establishing this program for foreign food safety audits and food and facility certifications will help us prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply. Widespread participation and broad acceptance of audits and certifications under the program will help increase efficiency by eliminating redundant auditing to assess foreign suppliers' compliance with the FD&C Act.

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.

4. Efforts to Identify Duplication and Use of Similar Information

The rulemaking underlying this information collection ("Third-Party rule") updates current regulations regarding food safety. We are unaware of regulations that would duplicate the information collection.

5. Impact on Small Businesses or Other Small Entities

In the agency's Final Regulatory Impact Analysis (FRIA) (found under Docket No. FDA-2011-N-0146), we proffer three scenarios discussing the impact of the regulations. While each scenario contemplates potential costs, we believe the rulemaking imposes minimal burden to respondents.

6. Consequences of Collecting the Information Less Frequently

Information collection occurs 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

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the Federal Register on July 29, 2013 (78 FR 45781). Comments received in response to the rulemaking are discussed in the agency's final rule that published in the Federal Register on November 27, 2015 (80 FR 74570). As finalized, the estimated information collection burden has decreased from estimates provided in the agency's proposed rule.

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

The Third-Party rule 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.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Respondents to the collection are eligible entities seeking audits, certification, and/or recertification by accredited certification bodies participating in our program, and accreditation bodies (ABs) and certification bodies (CBs) seeking to comply with the recognition requirements of the rule. 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 certification body.

12 a. Annualized Hour Burden Estimate

In the Federal Register publication of the Third-Party rule (80 FR 74570), we considered three scenarios for the participation rate of VQIP importers and their associated foreign suppliers in a 10-year period. Because scenario no. 3 reflects the highest-end estimates we use those figures for this analysis. Estimates associated with each scenario is discussed and may be found in the agency's rulemaking under Docket No. FDA-2011-N-0146 (80 FR at 74639).

Recordkeeping Burden

Under Scenario 3, the total one-time recordkeeping burden by 25 recognized ABs and 208 CBs accredited under the third-party program is estimated at 58,570 hours. The total annual recordkeeping burden by 25 recognized ABs and 208 CBs accredited under the third-party program is estimated at 6,253 hours . For the purpose 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.

SCENARIO 3; Estimated One-Time Recordkeeping Burden[1]

21 CFR Part 1, Subpart M	No. of Recordkeepers	No. of Records per Recordkeeper	Total One-Time Records	Avg. Burden per Recordkeeping (in hours)	Total Hours
§1.615	25	1	25	2	50
§1.645	208	1	208	2	416
§1.624(d)	25	1	25	160	4,000
§1.657(d)	208	1	208	160	33,280
Contract modification	25	8.79	220	2	440
§1.651	208	48.5	10,088	2	20,176
§1.653(b)(2)	208	1	208	1	208
Total One-Time Recordkeeping Burden					**58,570**

[1] There are no operations and maintenance costs associated with one-time recordkeeping burden.

SCENARIO 3; Estimated Annual (Recurring) 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
§1.625	25	426	10,650	0.25	2,663
§1.624(c)	25	1	25	8	200
§1.657(d)	208	1	208	8	1,664
§1.652	208	48.5	10,088	0.83	837
§1.653(b)(2)	208	48.5	10,088	0.83	837
§1.656(c)	208		52	1	52
Total Annual Recordkeeping Burden					**6,253**

[1] There are no operations and maintenance costs associated with annual recordkeeping burden.

Reporting Burden

Under Scenario 3, the total one-time reporting burden by 25 recognized ABs and 208 CBs accredited under the third-party program is estimated at 2,080 hours. The total annual reporting burden by 25 recognized Abs and 208 CBs accredited under the program is estimated at 7,919.

SCENARIO 3; Estimated One-Time Reporting Burden[1]

21 CFR Part 1; Subpart M	No. of Respondents	No. of Responses per Respondent	Total one-time Responses	Avg. Burden per Response (in hours)	Total Hours
§1.630	25	1	25	80	2,000
§1.670(a-b)	1	1	1	80	80
Total One-time Reporting Burden					**2,080**

[1] There are no operating or maintenance costs associated with one-time reporting.

SCENARIO 3; Estimated Annual (Recurring) Reporting Burden[1]

21 CFR Part 1; Subpart M	No. of Respondents	No. of Responses per Respondent	Total one-time Responses	Avg. Burden per Response (in hours)	Total Hours
§1.634	25	1	25	8	200
§1.673	1	1	1	10	10
§1.623(a)	25	8.79	220	0.25	55
§1.623(b)	25	1	25	0.25	6
§1.653(b)(1)	208	48.5	10,088	0.25	2,522
§1.656(a)[2]	207	48.5	10,040	0.25	2,510
§1.656(a)[3]	207	48.5	10,040	0.25	2,510
§1.656(a)[4]	1	55.4	55	0.25	14
§1.656(b)[5]	207	1	207	0.25	52
§1.656(b)[6]	1	1	1	0.25	1
§1.656(c)	208	0.25	52	0.25	13
§1.656(e)[7]	208	0.25	52	0.25	13
§1.656(e)[8]	207	0.25	52	0.25	13
Total Annual Reporting Burden					**7,919**

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

2. Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to their accrediting ABs.
3. Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to the FDA.
4. Annual reporting of regulatory audit reports by directly accredited CBs to the FDA.
5. Annual reporting of self-assessment by accredited CBs to their recognized ABs.
6. Annual reporting of self-assessment by directly-accredited CBs to the FDA.
7. Annual reporting of serious risk to public health by CBs accredited under the third-party program to eligible entities.

   Annual reporting of serious risk to public health by accredited CBs to their recognized ABs.

12b. Annualized Cost Burden Estimate

We estimate the annualized cost burden as follows:

SCENARIO 3: Annualized Cost

Eligible Entity	Audited by Certification Bodies accredited under other programs	Audited by Certification Bodies not accredited under any program	TOTAL Cost of Compliance
No. of section 801(q) entities	10	65	75
TP Compliance Cost	$227	$2,102	----------
Section 801(q) Compliance Cost	$2,270	$136,630	$138,900
No. of section 806 entities	801	5,359	6,160
TP Compliance Cost	$227	$2,102	----------
Section 806 Compliance Cost	$181,827	$11,264,618	$11,446,445
TOTAL TP Compliance Cost Scenario 3			$11,585,345

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

There are no capital costs associated with this information collection.

14. Annualized Cost to the Federal Government

In the economic analysis of the Third Party proposed rule, we estimated the annualized cost to FDA to administer the program (see Preliminary Regulatory Impact Analysis (PRIA) under Docket No. FDA-2011-N-0146). The administration of the Third Party proposed program includes review of initial and renewal applications for recognition and accreditation, monitoring ABs and CBs under the proposed program, and collection and dissemination of information. Under FSVP co-proposal Option 1, annualized cost to the FDA to administer the Third Party program is estimated at approximately $17.6 million (see Appendix B of the FSVP Third Party combined economic analysis; Table B10a). Under FSVP co-proposal Option 2, annualized cost to the FDA is estimated at approximately $17.0 million (see Appendix B; Table B10b). For purposes of the final rule we have retained this estimate.

15. Explanation for Program Changes or Adjustments

This is a new information collection request.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA will make available on its website a publicly available registry of recognized accreditation bodies and of accredited auditors/certification bodies, including the name of and contact information for such bodies. Such registry may provide information on auditors/certification bodies accredited by recognized accreditation bodies through links to the websites of such accreditation bodies.

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

We are not seeking approval not to display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.