FDA's Voluntary Qualified Importer Program;
Guidance for Industry

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) enables the Food and Drug Administration (FDA or the agency) to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA also requires FDA to establish a voluntary, fee-based program for the expedited review and importation of foods from importers who achieve and maintain a high level of control over the safety and security of their supply chains. This control includes importation of food from facilities that have been certified in accordance with FDA's program for Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (see FDA's third-party certification regulations at 21 CFR part 1, subpart M), as well as other measures that support a high level of confidence in the safety and security of the food they import. Expedited entry incentivizes importers to adopt a robust system of supply chain management and further benefits public health by allowing FDA to focus its resources on food entries that pose a higher risk to public health.

To implement this FSMA provision, FDA has developed guidance describing its policy regarding participation in FDA's Voluntary Qualified Importer Program (VQIP) by importers of food for humans or animals. The guidance explains the benefits VQIP importers can expect to receive; eligibility criteria for VQIP participation; instructions for completing a VQIP application; conditions that may result in revocation of participation in VQIP; and criteria for VQIP reinstatement following revocation. Accordingly FDA is requesting OMB approval of the information collection provisions contained in the guidance entitled, "*FDA's Voluntary Qualified Importer Program; Guidance for Industry*."

2. Purpose and Use of the Information Collection

Information collection provisions of the guidance facilitates expedited review and importation of food offered for importation by importers who voluntarily agree to participate in VQIP, and supports the establishment of an agency process, consistent with section 808 of the FD&C Act (21 U.S.C. 384d), for the issuance of a facility certification to accompany a food offered for importation by importers participating in VQIP.

Description of Respondents: Respondents to the collection of information are importers of human or animal food.

3. Use of Improved Information Technology and Burden Reduction

The guidance does not specifically recommend the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology for use by firms. Respondents may use whatever forms of information technology that bests assist them in retaining the appropriate records and making them available to regulatory officials. VQIP applications may be submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of any duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

While the information collection provisions apply to small and large businesses alike, FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

The VQIP guidance provides for an annual application process and the establishment and maintenance of a quality assurance program. We believe the frequency of collection imposes a minimal burden on respondents while allowing the agency to effectively administer the program. We believe less frequent collection would diminish the agency's ability to ensure the safety of food being imported into the United States.

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

There are no special circumstances associated with 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), FDA published a 60-day notice for public comment in the Federal Register of June 5, 2015 (80 FR 32136), Docket no. FDA-2011-N-0144. In response to the solicitation of comments regarding the information collection provisions, we received multiple comments. Two comments suggested that FDA's recordkeeping and reporting estimates were too low. Because neither comment provided justification for why the burden calculation might be too low or offered alternative calculations, we have retained our original estimates noting that, upon implementation of the program, we will again invite public comment on the information collection burden and make adjustments to our estimates accordingly. One comment attributed costs to the information collection but did not provide a basis for the calculations provided. We therefore have not adopted the comment, but again note that public input will be solicited on the information collection upon implementation of the program.

Finally, one comment objected to the provision regarding respondents obtaining a Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number and providing it to the agency. We have determined that the DUNS number is an appropriate unique facility identifier during Foreign Supplier Verification Program (FSVP) rulemaking. We expect that most VQIP importers will also be FSVP importers and will have obtained a DUNS number.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

FDA will protect confidential information in VQIP applications from disclosure, consistent with applicable statutes and regulations, including 5 U.S.C. 552(b)(4), 18 U.S.C. 1905, and 21 CFR part 20. We will share information in VQIP applications with other government agencies, such as United States Customs and Border Protection (CBP), in accordance with applicable law. This will allow CBP to recognize VQIP applicants and the VQIP foods they offer for entry into the United States.

11. Justification for Sensitive Questions

The information collection does not include questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Table 1 – Estimated One-Time Recordkeeping Burden[1]

Information Collection Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total One-Time Records	Avg. Burden per Recordkeeping	Total Hours
Quality Assurance Program (QAP) preparation	200	1	200	160	32,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate it will take a VQIP applicant no longer than 10 hours to develop its Quality Assurance Program (QAP), including compiling its company profile, organizational structure, corporate quality policy statement, procedures for QAP implementation, food safety and food defense policies and procedures, and procedures for record retention. On average, the preparation of a QAP by a VQIP applicant is estimated at approximately 160 hours (110 + 40 + 10). In estimation of the one-time recordkeeping burden to prepare a QAP manual, we assume that VQIP importers do not already have a similar manual in place (e.g., food safety plan under the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food regulation (21 CFR part 117); food defense plan under the Focused Mitigation Strategies to Protect Food Against Intentional Adulteration regulation (IA regulation)

(21 CFR part 121). The one-time recordkeeping burden for 200 VQIP applicants to prepare QAPs is estimated at 32,000 hours (200 applicants x 160 hours/applicant) (see Table 1). To the extent that some importers do have QAP manuals in place, the burden would be overestimated.

Table 2 – Estimated Annual Recordkeeping Burden[1]

Information Collection Activity	Number of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
QAP modification	200	1	200	16	3,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

A VQIP importer is expected to update its QAP on an ongoing basis. We estimate it would take 10 percent of the effort to prepare the QAP, or 16 hours, to update the QAP each year. Therefore, we estimate the annual recordkeeping burden of modification of the QAP for 200 VQIP importers at 3,200 hours (200 importers x 16 hours/importer). The VQIP food defense security criterion is similar to the Food Defense Plan requirement under § 121.126 (21 CFR 121.126) in the IA regulation. Under the IA regulation, the food defense plan must include the written identification of actionable process steps, focused mitigation strategies, procedures for monitoring, corrective action procedures, and verification procedures. Therefore, we estimate that, on average, it would take 40 hours for an applicant to prepare the food defense portion of the VQIP QAP.

Table 3 – Estimated One-Time Reporting Burden[1]

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total One-Time Responses	Avg. Burden per Response	Total Hours
Initial VQIP application	100	1	100	80	8,000
Initial VQIP application w/additional information	100	1	100	100	10,000
TOTAL					18,000

[1] There are no capital or operating and maintenance costs associated with the collection of information.

The guidance will inform food importers of application procedures for VQIP. We estimate that up to 200 qualified importers will be accepted in the first year of VQIP. We estimate that it will take 80 person-hours to compile all the relevant information and complete the application for the VQIP program. For the purpose of this analysis, we assume that 50 percent of all applications received will require additional information and it would take an additional 20 person-hours by the importer to provide that information. Therefore, we estimate that 100 importers will spend 8,000 hours (80 hours/importer x 100 importers) and 100 importers will spend 10,000 hours (100 hours/importer x 100 importers) to submit their initial VQIP applications for a total one-time reporting burden of 18,000 hours (see Table 3).

Table 4 – Estimated Annual Reporting Burden[1]

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Subsequent year VQIP application	200	1	200	20	4,000
Request to reinstate participation	2	1	2	10	20
TOTAL					4,020

[1] There are no capital or operating and maintenance costs associated with the collection of information.

The guidance states that each VQIP participant will submit to FDA a notice of intent to participate in VQIP on an annual basis. We expect that each of the expected 200 importers in VQIP would apply in the subsequent year to participate in VQIP. We expect that an application to participate in VQIP in a subsequent year will take significantly less time to prepare than the initial application. We use 25 percent of the amount of effort to prepare and submit the initial application for acceptance in VQIP. Therefore, it is expected that, on average, each VQIP importer will spend 20 hours to complete and submit a VQIP application for each subsequent year. The annual burden of completing a subsequent year application to participate in VQIP status by 200 importers is estimated at 4,000 hours (200 applications x 20 hours/application) (see Table 4).

Finally, we have added to the VQIP estimated annual reporting burden an estimate of the burden associated with importers' requests to reinstate participation in VQIP after their participation is revoked. We believe most participants will not need to use this provision, and we have included an estimate that reflects this. Upon implementation of the VQIP, we will reevaluate our estimate for future OMB submission and revise it accordingly.

12 b. Annualized Cost Burden Estimate

FDA estimates an annualized cost to respondents based on an average hourly wage equivalent to a GS-12/Step-1 level in the locality pay area of Washington-Baltimore in 2012, approximately $35.88/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to be $71.76/hour. Thus, the overall estimated annualized cost incurred by the respondents for the information collection contained in the guidance is approximately $3,300 (46 x 71.76).

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to Federal Government

At this time the agency estimates no annualized cost to the Federal government for the information collection. Under FSMA the agency has issued several regulations estimating associated costs. We believe that costs associated with the administration of VQIP will be absorbed by the other agency programs established under these regulations.

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 post a publicly available list of approved VQIP importers on its webpage at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm448728.htm. VQIP importers may choose not to be listed on the VQIP importers list. A VQIP importer's decision to opt out of being listed on the publicly available list of approved VQIP importers will not have any effect on its participation. The agency has no plans for publication of information from this information collection.

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

Display of the expiration date for OMB approval of the information collection is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.