4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0144]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Qualified Importer Program

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: Submit written comments (including recommendations) 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 submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0840. 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-12M, 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.

Agency Information Collection Activities; Proposed Collection; Comment Request; FDA's Voluntary Qualified Importer Program

OMB Control Number 0910-0840--Extension

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) enables FDA 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 recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production. Under FSMA, those that import food have a responsibility to ensure that their suppliers produce food that meets U.S. safety standards.

FSMA also requires FDA to establish a voluntary, fee-based program for the expedited review and importation of foods by 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 under FDA's accredited third-party certification program, 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.

Section 302 of FSMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding new section 806, Voluntary Qualified Importer Program (VQIP) (21 U.S.C. 384b). Section 806(a)(1) of the FD&C Act directs FDA to establish this voluntary program for the

expedited review and importation of food, and to establish a process for the issuance of a facility certification to accompany food offered for importation by importers participating in VQIP. Section 806(a)(2) directs FDA to issue a guidance document related to participation in, revocation of such participation in, reinstatement in, and compliance with VQIP. Accordingly, in the *Federal Register* of November 14, 2016 (81 FR 79502), FDA published a notice announcing the availability of a final guidance for industry entitled "FDA's Voluntary Qualified Importer Program." The guidance is available from our website at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-voluntary-qualified-importer-program.

In the *Federal Register* of February 5, 2020 (85 FR 6556) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. We estimate the burden of the information collection as follows:

Table 1.--One-Time Recordkeeping Burden[1]

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	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.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our one-time recordkeeping burden estimate. 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)). We continue to use the recordkeeping burden of preparing a food safety plan under part 117, 110 hours, as a proxy for the burden to prepare QAP Food Safety Policies and Procedures. We continue to estimate that, on average, it would take 40 hours for an applicant to prepare the food defense portion of the VQIP QAP, similar to the estimated burden for preparing a food defense plan under the IA regulation. We also continue to estimate it will take a VQIP applicant no longer than 10 hours to develop the portion of its QAP that includes compiling its company profile, organizational structure, corporate quality policy statement, documentation of contracts, and procedures for record retention. Therefore, the one-time recordkeeping burden for 200 VQIP applicants to prepare QAPs is estimated at 32,000 hours (200 applicants × 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	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	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. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our annual recordkeeping burden estimate. 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 × 16 hours/importer).

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

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average 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 costs or operating and maintenance costs associated with this collection of information.

The guidance informs food importers of application procedures for VQIP. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our one-time reporting burden estimate. As we are still in the process of implementing this program, we continue to estimate that up to 200 qualified importers will be accepted in the upcoming 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 × 100 importers) and 100 importers will spend 10,000 hours (100 hours/importer × 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	Average 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 costs or operating and maintenance costs associated with this 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. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our annual reporting burden estimate. 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 × 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.

Dated: June 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-12755 Filed: 6/11/2020 8:45 am; Publication Date: 6/12/2020]