United States Food and Drug Administration

Voluntary Qualified Importer Program

OMB Control No. 0910-0840

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of FDA's Voluntary Qualified Importer Program (VQIP), a voluntary fee-based program that provides expedited review and import entry of human and animal foods into the United States. Program participants may import products to the United States with greater speed and predictability, avoiding unexpected delays at the point of import entry. Importers interested in applying can start their application (Form FDA 4041) by submitting a notice of intent to participate after setting up an account through the FDA Industry Systems (FIS) website at *https://www.access.fda.gov*, which includes a VQIP Portal User Guide. To participate, importers must meet eligibility criteria and pay a user fee that covers costs associated with FDA's administration of the program. Consistent with section 743(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379j-31(b)(1)), FDA annually publishes a schedule of fees applicable to VQIP in the *Federal Register*.

To assist respondents with the information collection, we developed the guidance document entitled, "FDA's Voluntary Qualified Importer Program" (issued November 2016, updated July 2023 to change the PRA burden statement address), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fdas-voluntary-qualified-importer-program*. The guidance document is prepared in a question-and-answer format and discusses eligibility criteria; includes instruction for completing a VQIP application; explains conditions that may result in revocation of participation as well as criteria for reinstatement; and communicates benefits VQIP importers can expect to receive under the program. The guidance also discusses preparation of the "Quality Assurance Program (QAP)," a compilation of written policies and procedures used to ensure adequate control over the safety and security of foods being imported. The guidance document was developed and issued consistent with FDA Good Guidance Practice regulations in 21 CFR part 10.115, which provides for public comment at any time.

Accordingly, we request approval for the information collection provisions contained in the guidance and Form FDA 4041, as discussed in this supporting statement.

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 information collection are persons that bring food, or cause food to be brought, from a foreign country into the customs territory of the United States (section 806 of the FD&C Act (21 U.S.C. 384b)) as a VQIP importer. A VQIP importer can be located outside the United States. Persons who may be a VQIP importer include the manufacturer, owner, consignee, and importer of record of a food, provided that the importer can meet all the criteria for participation.

3. Use of Improved Information Technology and Burden Reduction

FDA leverages information technology systems to facilitate electronic submissions of VQIP applications to FDA. To submit a VQIP application, participants establish an online account on the FDA Industry Systems Web site at www.access.fda.gov. The information in the online account will auto populate into the VQIP application (Form FDA 4041). Additional information on completing and submitting a VQIP application is provided in Section G of the guidance and the VQIP Portal User Guide (https://www.fda.gov/media/113346/download). 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, but respondents should establish an online account on the FDA Industry Systems Web site. Respondents can update or change information in the online account at any time.

Once the application has been reviewed and approved by FDA, an email is sent to the main contact person specified in the VQIP application. Approved VQIP participants will receive an invoice sent via email to be paid prior to October 1st of the calendar year. Instructions and methods of payment may be found by visiting the Voluntary Qualified Importer Program User Fees page (https://www.fda.gov/industry/fda-user-fee-programs/voluntary-qualified-importer-program-user-fees) and selecting the current Federal Register Notice.

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, it imposes no undue burden on small entities. At the same time, 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 guidance provides for an annual application process and the establishment and maintenance of a quality assurance program (QAP). 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), we published a 60-day notice for public comment in the *Federal Register* of May 11, 2023 (88 FR 30315). 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

The Privacy Act of 1974

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted includes point of contact name, employer tax identification number, work email address, work telephone number, and work fax telephone number. FDA 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 Act do not apply. Specifically, the contractor or 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.

The Freedom of Information Act

Under the Freedom of Information Act (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, 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

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We estimate the burden of the information collection as follows:

Table 1.—Estimated Annual Reporting Burden

Reporting Using FIS System VQIP Portal/Form FDA 4041	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial VQIP application	5	1	5	180	900
Application Renewals – subsequent year	6	1	6	20	120
Requests for reinstatement	2	1	2	10	20
Total					1,040

Table 2.—Estimated Annual Recordkeeping Burden

VQIP Participant Records Consistent with Implementing Guidance	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Quality Assurance Program (QAP) preparation	5	1	5	160	800
QAP maintenance and updates	6	1	6	16	96
Total					896

The burden hour total for this ICR is 1,936 hours (1,040 + 896).

We assume the average burden required for the respective reporting and recordkeeping activities for both initial and continued participation in the program remain constant.

12b. Annualized Hour Burden Estimate

We assume an annualized cost to respondents commensurate with an average hourly wage of a GS-12/Step-1 level in the locality pay area of Washington-Baltimore in (2023 OPM schedule: $45.14/hour).[1] Doubling this wage to account for fringe benefits, we calculate an

[1] See OPM 2023 Salary Table at: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/23Tables/html/DCB_h.aspx

average hourly cost of $90.28/hour for reporting and recordkeeping. We then multiply the total number of burden hours (1,936) by the average hourly cost, for a total cost estimate of $174,782.

VQIP Participant Reporting and Records Consistent with Implementing Guidance	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Professional services commensurate with GS-12/Step-1	1.936	$90.28	$174,782

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

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

14. Annualized Cost to Federal Government

We assume, using FY 22-FY 23 appropriations request data, expenditure reporting, and allocated among our agency import program activities offset against the $6,000,000 in collected VQIP user fees, the cost to administer the VQIP program information collection is $3,435.47.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall adjustment decrease of 1,844 hours and a corresponding decrease of 18 responses. Since our last request for OMB approval of the information collection, we have adjusted our estimate of the number of respondents based on actual participation in the program. This results in a decrease of 500 hours to the currently approved recordkeeping burden attributed to initial VQIP applications with additional information. We assume the average burden required for the respective reporting and recordkeeping activities for both initial and continued participation in the program remain constant.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA makes a publicly available list of approved VQIP importers on its webpage at https://www.fda.gov/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip-public-list-approved-vqip-importers. VQIP importers may choose not to be listed. 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

FDA will display the OMB expiration date as required by 5 CFR 1320.8. We display the OMB expiration date as part of the Federal Industry Systems landing page. The agency will continue its efforts to increase the visibility of the PRA burden statement displayed in electronic format as

our allocated resources permit.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.