paper-based methods, electronic methods, or both)?

- If not currently exchanging data with trading partners in a fully electronic manner, will you be able to in the near future? If not, what are the barriers? Elaborate on why or how, as appropriate. Please specify issues related to:
- accessibility of necessary software and hardware;
- cost to obtain, install, and maintain necessary software and hardware, particularly if it is prohibitively expensive;
- integration of necessary software and hardware into business practices, such as with wholesale distributors;
- other relevant information related to feasibility of dispensers with 25 or fewer full-time employees to conduct interoperable, electronic tracing of product at the package level.
- What type of software systems and hardware do you currently utilize to facilitate the electronic exchange of DSCSA-related data for transactions of products?
- What new or modified software systems and hardware do you anticipate putting in place to comply with the interoperable, electronic tracing requirements?
- How likely are you to change and upgrade your existing software systems that are already in use so that you can comply with the interoperable, electronic tracing requirements?
- Have you or do you plan to connect your system(s) with your trading partner(s) (*e.g.,* manufacturer(s), repackager(s), or wholesale distributor(s)) in order to facilitate electronic DSCSA-related data exchange? If so, have you experienced technical issues when attempting to establish connectivity? If not, how do you or how do you plan to manage electronic DSCSA-related data received from an upstream trading partner (*e.g.,* maintain the data in your dispenser system or use a third-party agreement for another entity to confidentially maintain the DSCSA-related data on your behalf (*e.g.,* use of a secure web portal provided by your wholesale distributor))?
- Have you considered data integrity and security concerns when establishing agreements with third-party entities (*e.g.,* solution providers or wholesale distributors) for electronic data exchange and maintenance?
- Have you ever received transaction information from a trading partner, such as your wholesale distributor, that does not match the product that you received? If so, how long did it take to resolve the discrepancy on average? What if any unique challenges arose from these situations? How often does this happen?
- If you currently routinely scan a 2D data matrix barcode, how often do you receive a 2D data matrix barcode of the product identifier that cannot be scanned or read? Why are you unable to scan or read the 2D data matrix barcode (*e.g.,* barcode quality, scanner performance, software issue) and what is your process for handling these situations, including when manual steps are taken by your staff when an automated process was inadequate or failed?
- If you currently routinely scan the 2D data matrix barcode, how often you encounter a 2D data matrix barcode with missing or inaccurate data? What are the reasons for this and what is your process for handling these situations, including when manual steps are taken by your staff when an automated process was inadequate or failed?
- What new demands do you expect the DSCSA requirements in section 582(g)(1) of the FD&C Act to have on your current staff resources?
- How long do you expect it will take to train staff on the new requirements, how to use any new software or hardware, and any process changes? What additional resources do you anticipate needing to comply with the interoperable, electronic tracing requirements?
- Are there additional challenges not already identified when operationalizing new systems and processes for interoperable, electronic tracing of products at the package level required under section 582(g)(1) of the FD&C Act (*i.e.,* enhanced product tracing or enhanced verification)?

Stakeholders may provide other relevant information that may inform the development of the small dispenser assessment under the DSCSA.

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17140 Filed 8–9–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1529]

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 September 11, 2023.

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: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Voluntary Qualified Importer Program

OMB Control Number 0910–0840—Extension

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**.

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.

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 Paperwork Reduction Act 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 10.115, which provides for public comment at any time.

In the **Federal Register** of May 11, 2023 (88 FR 30315), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Reporting using FIS VQIP portal/form FDA 4041	Number of respondents	Number 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

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

VQIP participant records consistent with implementing guidance	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Quality Assurance Program (QAP) preparation	5	1	5	160	800
QAP maintenance and updates	6	1	6	16	96
Total					896

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

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

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2186]

Request for Nominations on the Tobacco Products Scientific Advisory Committee—Small Business Pool

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any small business tobacco manufacturing industry organizations interested in participating in the selection of a nonvoting industry representative to serve on the Tobacco Products Scientific Advisory Committee for the Center for Tobacco Products notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to be included in a pool of individuals to represent the interests of the small business tobacco manufacturing industry on the Tobacco Products Scientific Advisory Committee. A nominee may either be