

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

self-nominated or nominated by an organization to serve as a nonvoting industry representative. This position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any small business tobacco manufacturing industry organization interested in participating in the selection of appropriate nonvoting members to represent industry interests must send a letter stating that interest to the FDA by September 11, 2023, (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by September 11, 2023.

ADDRESSES: All statements of interest from small business tobacco manufacturing industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent to CAPT Serina Hunter-Thomas (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm>. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website <http://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Office of Science, Center for Tobacco Products, Food and Drug Administration, Center for Tobacco Products Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373 (choose Option 5), or by email: TPSAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency intends to add nonvoting industry representative(s) to the following advisory committee:

I. Tobacco Products Scientific Advisory Committee

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner of FDA (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating

to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

The Committee includes three nonvoting members who represent industry interests. These members include one representative representing the interests of the tobacco manufacturing industry, one representative representing the interests of tobacco growers, and one representative representing the interests of the small business tobacco manufacturing industry, which may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee.

With this notice, nominations are sought for the following positions: A pool of individuals, with varying areas of expertise, to represent the interests of the small business tobacco manufacturing industry on a rotating, sequential basis.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward

all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women, and men, members of all racial and ethnic groups and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

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-2010-N-0583]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Radioactive Drug Research Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 0910-0053. 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