must send a letter stating that interest to FDA by October 15, 2018, (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by October 15, 2018.

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 Caryn Cohen (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal at: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at: *https://www.fda.gov/AdvisoryCommittees/default.htm.*

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

SUPPLEMENTARY INFORMATION: The Agency intends to add a nonvoting industry representative to represent the interests of the small business tobacco manufacturing industry to the following advisory committee:

I. Tobacco Products Scientific Advisory Committee

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner of Food and Drugs (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 of the interests of the tobacco manufacturing industry; one representative of the interests of tobacco growers; and one representative of 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 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: September 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19922 Filed 9–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0920]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

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: Fax written comments on the collection of information by October 15, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0751. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food—21 CFR Part 117

OMB Control Number 0910–0751—Extension

This information collection supports FDA regulations. As amended by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), the Federal Food, Drug, and Cosmetic Act (FD&C Act) enables the Agency to better protect the 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. Specifically, section 418 of the FD&C Act (21 U.S.C. 350g) sets forth requirements for hazard analysis and risk-based preventive controls for facilities that produce food for human consumption. To implement these provisions, regulations were codified under 21 CFR part 117—Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. The regulations establish requirements for a written food safety plan; hazard analysis preventive controls; monitoring; corrective actions and corrections; verification; supply-chain program; recall plan; and associated records, and became effective November 16, 2015. Currently, we continue to evaluate burden associated with the information collection requirements; however, for purposes of extending the information collection, we retain the currently approved figures as shown in the tables below.

In the **Federal Register** of June 1, 2018 (83 FR 25466), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received stating that our estimate of burden associated with creating a food safety plan was too low and suggested a much higher figure. We appreciate this comment. However, because the annual burden is based on an industry average and because we continue to evaluate this relatively new collection, we are not adjusting our current estimate. At the same time, we continue to invite comment so that we might better refine our estimates for all elements of the collection.

Our estimate of the burden for the information collection is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
117.201(e); qualified facility	37,134	0.5	18,567	0.5 (30 minutes)	9,284

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
117.126(c) and 117.170(d); food safety plan and reanalysis	46,685	1	46,685	110	5,135,350
117.136; assurance records	16,285	1	16,285	0.25 (15 minutes)	4,071
117.145(c); monitoring records	8,143	730	5,944,390	0.05 (3 minutes)	297,220
117.150(d); corrective actions and corrections records	16,285	2	32,570	1	32,570
117.155(b); verification records	8,143	244	1,986,892	0.05 (3 minutes)	99,345
117.160; validation records	3,677	6	22,062	0.25 (15 minutes)	5,515
117.475(c)(7)–(9); supplier records	16,285	10	162,850	4	651,400
117.180(d); training records for preventive controls qualified individual	46,685	1	46,685	0.25 (15 minutes)	11,671
Total					6,237,142

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
117.201(e); disclosure of food manufacturing facility address	37,134	1	37,134	0.25 (15 minutes)	9,284

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

As stated previously, we retain the currently approved burden for the information collection. These figures are based on our regulatory impact analysis in support of the final rule on preventive controls for human food, which published in the **Federal Register** of September 17, 2015 (80 FR 55908). Using Agency data, we estimated the number of food facilities that we believe are subject to the regulations. We base our estimate of the time necessary for the individual reporting, recordkeeping, and third-party disclosure activities on our experience with similar information collections.

Dated: September 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19911 Filed 9–12–18; 8:45 am]

BILLING CODE 4164–01–P