materials must be publicly available or able to be made public.

Virginia Mackay-Smith,

Associate Director.

[FR Doc. 2019–12636 Filed 6–14–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Center for State, Tribal, Local and Territorial Support (CSTLTS), CDC/ATSDR Tribal Advisory Committee (TAC) Meeting and 19th Biannual Tribal Consultation Session

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR), announces the following meeting and Tribal Consultation Session. The meetings are being hosted by CDC/ATSDR in-person only and are open to the public. Attendees must pre-register for the event by Friday, July 19, 2019, at the following link: *https://www.cdc.gov/tribal/consultation-support/tac/index.html.*

DATES: The meeting will be held on August 13–14, 2019.

August 13, 2019

- 8:00 a.m.–9:30 a.m., EDT—Tribal Caucus (Open only to elected tribal officials and by invitation)
- 9:30 a.m.–5:45 p.m., EDT—CDC/ATSDR TAC Meeting (Open to the public)

August 14, 2019

- 8:00 a.m.–9:30 a.m., EDT—Tribal Caucus (Open only to elected tribal officials and by invitation)
- 9:30 a.m.–5:45 p.m., EDT—CDC/ATSDR TAC Meeting (Open to the public)

ADDRESSES: Harrah's Cherokee, 77 Casino Drive, Cherokee, NC 28719.

FOR FURTHER INFORMATION CONTACT: Captain Carmen Clelland, PharmD, MPA, MPH, Director, Office of Tribal Affairs and Strategic Alliances, Center for State, Tribal, Local and Territorial Support, CDC, 4770 Buford Highway, Mailstop V18–4, Atlanta, GA 30341–3717; telephone (404) 498–0300; *Tribalsupport@cdc.gov.*

SUPPLEMENTARY INFORMATION: This meeting is being held in accordance with Presidential Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of November 5, 2009, and September 23, 2004, Consultation and Coordination with Indian Tribal Governments.

Purpose: The purpose of the TAC and consultation meetings is to advance CDC/ATSDR support for and collaboration with American Indian and Alaska Native (AI/AN) tribes and to improve the health of AI/AN tribes by pursuing goals that include assisting in eliminating the health disparities faced by AI/AN tribes; ensuring that access to critical health and human services and public health services is maximized to advance or enhance the social, physical, and economic status of American Indian and Alaskan Native people; and promoting health equity for all Indian people and communities. To advance these goals, CDC/ATSDR conducts government-to-government consultations with elected tribal officials or their authorized representatives. Consultation is an enhanced form of communication that emphasizes trust, respect, and shared responsibility. It is an open and free exchange of information and opinion among parties that leads to mutual understanding.

Matters To Be Considered: The agenda will include, but not limited to, discussions on securing sustainable funding to Indian Country, ensuring a tribal voice in CDC policy and programs, and current CDC priorities. The discussion topics are subject to revision as prioritize change. The TAC Meeting and Biannual Tribal Consultation Session will provide opportunities for elected AI/AN tribal officials to speak openly about the public health issues affecting their tribal nations. Tribal nations also will have an opportunity to present testimony about tribal public health issues. All elected tribal officials are encouraged to submit written testimony by 5:00 p.m., EDT, Friday, July 19, 2019 to Captain Carmen Clelland, Pharm, MPA, MPH, Director, Office of Tribal Affairs and Strategic Alliances via mail to 4770 Buford Highway, Mailstop V18–4, Atlanta, GA 30341–3717, or by email at *TribalSupport@cdc.gov.* Elected tribal officials can find guidance to assist in developing tribal testimony for CDC/ATSDR at *www.cdc.gov/tribal/consultation-support/index.html.* Please submit tribal testimony on official tribal letterhead.

Based on the number of elected tribal officials giving testimony and the time available, it may be necessary to limit the time for each presenter.

Additional information about the TAC, CDC/ATSDR's Tribal Consultation Policy, and previous meetings can be found at *www.cdc.gov/tribal/consultataion-support/index.html.* Agenda items are subject to change as priorities dictate.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–12724 Filed 6–14–19; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0721]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and Issue Certifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 July 17, 2019.

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 0910–0331. 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.

Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications—21 CFR Part 1; Subpart M

OMB Control Number 0910–0750—Extension

FDA provides for accreditation of third-party certification bodies (CBs) to conduct food safety audits of eligible foreign food facilities, and issue food and facility certifications, pursuant to the FDA Food Safety Modernization Act. In accordance with 21 CFR part 1.600, subpart M, FDA uses certifications issued by accredited third-party CBs in deciding whether to admit certain imported food into the United States that FDA has determined poses a food safety risk and in deciding whether an importer is eligible to participate in a program for expedited review and entry of food imports. Except for limited circumstances in which we may directly accredit CBs to participate in the accredited third-party audits and certification program, we will recognize accreditation bodies (ABs) to accredit third-party CBs. Use of accredited third-party CBs and food and facility certifications helps us prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply. This collection of information increases efficiency by reducing the number of redundant audits to assess compliance with applicable food safety requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA regulations.

We estimate that there are about 200,000 foreign food and feed exporters that offer their food and feed for import into the United States. These foreign food and feed exporters include approximately 130,000 food and feed production facilities and approximately 71,000 farms. A proportion of these foreign food and feed exporters may offer food subject to mandatory certification requirements under section 801(q) of the FD&C Act (21 U.S.C. 381(q)(3)). In that case, the eligible entities must either comply with this collection of information to obtain certification from a CB accredited under the third-party program to continue exporting their food products into the United States, obtain certification from a foreign government designated by FDA, or lose their access to U.S. markets. We assume that in any given year, 75 foreign food and feed exporters will be subject to section 801(q) of the FD&C Act.

We estimate that 25 ABs will accredit CBs that will conduct food safety audits of foreign eligible entities that offer food or feed for import to the United States. We also estimate that approximately 207 CBs accredited by the 25 AB applicants will comply with the collection of information to participate in the program. In addition, we expect that one CB will apply and participate in the third-party program via direct accreditation by FDA under this collection of information.

In the **Federal Register** of February 20, 2019 (84 FR 5084), we published a 60-day notice requesting public comment on the proposed collection of information. Several comments were submitted, however only those responsive to the information collection topics solicited are addressed here.

(Comment 1) One comment suggested that the Agency should conduct all food safety audits instead of allowing third-party entities to conduct them, which would allow for greater accountability.

(Response) With current resources, we do not have the ability to conduct food safety audits for the thousands of foreign suppliers that could potentially be interested in using this program to establish eligibility for Voluntary Qualified Importer Program under section 806 of the FD&C Act (21 U.S.C. 384b) or meet the certification requirements under section 801(q) of the FD&C Act. With accredited third-party CBs and ABs, we can leverage their food safety activities to benefit our system of public food safety assurances. The regulation for accreditation of third-party CBs includes requirements for the accredited CBs to demonstrate their competence and capability to determine an eligible entity's compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. In leveraging private food safety activities, we can prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply.

(Comment 2) One comment suggested that there would be less burden for the public to deal directly with FDA instead of a third party.

(Response) The Third-Party Program reduces burden for the public. Widespread participation and broad acceptance of audits and certifications under the program helps increase efficiency by eliminating redundant auditing to assess foreign suppliers' compliance with the FD&C Act and FDA regulations.

(Comment 3) One comment offered that the Third-Party Program is a resourceful and competitive way to perform food safety audits and issue certifications.

(Response) We agree with this comment. The use of accredited third-party CBs and food and facility certifications helps us prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply. This collection of information increases efficiency by reducing the number of redundant audits to assess compliance with applicable food safety requirements of the FD&C Act and FDA regulations.

FDA estimates the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part 1; subpart M	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 1.615 [2]	7	1	7	2	14
§ 1.645 [2]	68	1	68	2	136
§ 1.624(d) [2]	7	1	7	160	1,120
§ 1.657(d) [2]	68	1	68	160	10,880
Contract modification [2]	7	9	63	2	126
§ 1.651 [2]	68	48.5	3,298	2	6,596
§ 1.653(b)(2) [2]	68	1	68	1	68
§ 1.625	25	426	10,650	0.25 (15 minutes)	2,663

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR part 1; subpart M	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 1.624(c)	25	1	25	8	200
§ 1.657(d)	208	1	208	8	1,664
§ 1.652	208	48.5	10,088	0.083 (5 minutes)	837
§ 1.653(b)(2)	208	48.5	10,088	0.083 (5 minutes)	837
§ 1.656(c)	208	0.25	52	1	52
Total Annual Recordkeeping Burden					25,193

[1] There are no capital costs or operating and maintenance costs associated with annual recordkeeping burden.
[2] Initial burden for an AB seeking recognition or a CB seeking accreditation.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 1; subpart M	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
§ 1.630 [2]	7	1	7	80	560
§ 1.670 [2]	1	1	1	80	80
§ 1.634	25	1	25	8	200
§ 1.672	1	1	1	10	10
§ 1.623(a)	25	9	225	0.25 (15 minutes)	56
§ 1.623(b)	25	1	25	0.25 (15 minutes)	6
§ 1.653(b)(1)	208	48.5	10,088	0.25 (15 minutes)	2,522
§ 1.656(a) [3]	207	48.5	10,040	0.25 (15 minutes)	2,510
§ 1.656(a) [4]	207	48.5	10,040	0.25 (15 minutes)	2,510
§ 1.656(a) [5]	1	55.4	55	0.25 (15 minutes)	14
§ 1.656(b) [6]	207	1	207	0.25 (15 minutes)	52
§ 1.656(b) [7]	1	1	1	0.25 (15 minutes)	1
§ 1.656(c)	208	0.25	52	0.25 (15 minutes)	13
§ 1.656(e) [8]	208	0.25	52	0.25 (15 minutes)	13
§ 1.656(e) [9]	207	0.25	52	0.25 (15 minutes)	13
Total Annual Reporting Burden					8,560

[1] There are no capital costs or operating and maintenance costs associated with annual reporting.
[2] Initial burden for an AB seeking recognition or a CB seeking accreditation.
[3] Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to their accrediting ABs.
[4] Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to FDA.
[5] Annual reporting of regulatory audit reports by directly accredited CBs to FDA.
[6] Annual reporting of self-assessment by accredited CBs to their recognized ABs.
[7] Annual reporting of self-assessment by directly-accredited CBs to FDA.
[8] Annual reporting of serious risk to public health by CBs accredited under the third-party program to eligible entities.
[9] Annual reporting of serious risk to public health by accredited CBs to their recognized ABs.

The total annual recordkeeping burden by 25 recognized ABs and 208 CBs accredited under the third-party program is estimated at 25,193 hours (see table 1). We assume that all ABs that apply for recognition in the program become recognized and all CBs that apply for accreditation are accredited. The total annual reporting burden by 25 recognized ABs and 208 CBs accredited under the program is estimated at 8,560 hours (see table 2). These estimates reflect a correction to the estimates published in the last 60-day notice, which did not include estimates for the initial burden needed to apply for entry into the program.

We have adjusted our burden estimate since the last OMB approval to reflect the decrease of burden associated with one-time recordkeeping and reporting activities and have revised our estimate to reflect the initial burden for new ABs seeking recognition and new CBs seeking accreditation. The adjustment resulted in decreases of 7,421 responses and 41,069 total burden hours.

Dated: June 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12703 Filed 6–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0350]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Tobacco Retailers on Tobacco Retailer Training Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of