appropriate licensing bodies and ombudsmen programs.

- A description of the organization's policies and procedures with respect to the withholding or removal of accreditation for failure to meet the accreditation organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.
- A description of all types (for example, full, partial) and categories (for example, provisional, conditional, temporary) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement identifying the types and categories that would serve as a basis for accreditation if CMS approves the accreditation organization.
- A list of all currently accredited MA organizations and the type, category, and expiration date of the accreditation held by each of them.
- A list of all full and partial accreditation surveys scheduled to be performed by the accreditation organization.
- The name and address of each person with an ownership or control interest in the accreditation organization.
- CMS also considers URAC's past performance in the deeming program and results of recent deeming validation reviews, or look-behind audits conducted as part of continuing federal oversight of the deeming program under § 422.157(d).

In accordance with section 1865(a)(3)(A) of the Act, the December 26, 2018 proposed notice (83 FR 66271) also solicited public comments regarding whether URAC's requirements met or exceeded the Medicare conditions of participation as an accrediting organization for MA HMOs and PPOs. We received no public comments in response to the December 26, 2018 proposed notice (83 FR 66271).

III. Provisions of the Final Notice

A. Differences Between URAC's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared the standards and survey process contained in URAC's application with the Medicare conditions for accreditation. Our review and evaluation of URAC's application for continued CMS approval were conducted as described in section II. of this final notice, and yielded the following:

- URAC amended its crosswalk to ensure current URAC standards are clearly cross-walked to our regulations, including the following regulatory requirements for Quality Improvement; Antidiscrimination, Confidentiality and Accuracy of Enrollee Records, Information on Advanced Directives, and Provider Participation Rules: §§ 422.101(f); 422.205(b); 422.110(a) through (b); 422.118(a); 422.128(b); 422.152(a) and (b), (e) through (g); 422.202(a) through (d); 422.206(a) through (b); 422.208(c), (e) through (g); 422.210(b); 422.212(a) through (d); and 422.216(f) through (h).
- URAC submitted additional information and/or documentation regarding its survey process that was intended to address: § 422.158(a)(2), (a)(3)(ii), (a)(3)(iii)(A) through (C), (a)(4)(ii) and (iii), (a)(6) through (10), and (b)(2).

B. Term of Approval

Based on the review and observations described in section II. of this final notice, we have determined that URAC's accreditation program requirements meet or exceed our requirements. Therefore, we approve URAC as a national accreditation organization with deeming authority for MA HMOs and PPOs, effective May 21, 2019.

V. Collection of Information Requirements

This notice announces the new term of approval for the URAC. It does not impose any information collection requirements (that is, reporting, recordkeeping or third-party disclosure requirements). Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

Dated: May 2, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–10586 Filed 5–20–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0801]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exports: Notification and Recordkeeping Requirements

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 June 20, 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 0910–0482. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Exports: Notification and Recordkeeping Requirements—21 CFR 1.101

OMB Control Number 0910–0482—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381) charges the Secretary of Health and Human Services, through FDA, with the responsibility of helping to ensure that exports of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products which are not to be sold in the United States

meet the requirements of the country to which the product is to be exported. The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or offered for sale in domestic commerce in the United States as allowed under section 801(e) of the FD&C Act. In general, the notification identifies the product being exported (*e.g.,* name, description, and in some cases, country of destination) and specifies where the notifications were sent. These notifications are sent only for an initial export. Subsequent exports of the same product to the same destination or to certain countries identified in section 802(b) of the FD&C Act (21 U.S.C. 382(b)) would not result in a notification to FDA.

The recordkeepers for this information collection are exporters of products that may not be sold in the United States who are regulated by the following FDA Centers: Center for Drug Evaluation and Research (CDER); Center for Biologics Evaluation and Research (CBER); Center for Devices and Radiological Health (CDRH); Center for Veterinary Medicine (CVM); Center for Food Safety and Applied Nutrition (CFSAN); and Center for Tobacco Products (CTP). Respondents to this collection of information maintain records demonstrating their compliance with the requirements in 21 CFR 1.101.

In the **Federal Register** of February 15, 2019 (84 FR 4473), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information 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
1.101(d) (CBER)	5	92	460	15	6,900
1.101(d) (CDER)	5	180	900	15	13,500
1.101(d) (CDRH)	160	1	160	15	2,400
Total					22,800

[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
1.101 (b), (c), (e) (CBER, CDER, CDRH, CFSAN, and CVM)	320	3	960	22	21,120
1.101(b) Office of International Programs only	1	189	189	22	4,158
1.101(b) (currently regulated Tobacco Products)	322	3	966	22	21,252
Total					46,530

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

We have adjusted our burden estimate, which has resulted in an overall decrease of 129,543 hours to the currently approved burden. The reporting burden estimate for CDRH has been adjusted to correct an error and corresponding miscalculation in the previous burden estimate and has been updated based on recent internal data. This adjustment contributed to the overall burden estimate reduction by eliminating 8,030 responses and 120,450 hours from the reporting burden estimate. CBER's estimated reporting burden for the information collection in table 1 reflects a decrease of 7,575 hours and a corresponding decrease of total annual responses (193 to 92). We attribute this adjustment to a normal variation in the number of submissions we received over the last few years. CTP's current number of respondents and recordkeeping burden hours in table 2 are expected to decrease by 23 respondents and 1,518 hours. This is based on summary derived from the monthly operational reports that manufacturers and importers of tobacco products are required to file with the Alcohol and Tobacco Tax and Trade Bureau.

Dated: May 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10537 Filed 5–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held of the National Vaccine Advisory Committee (NVAC). The meeting will be open to the public via teleconference; a public comment session will be held during the meeting.

DATES: The meeting will be held on Tuesday and Wednesday, June 4–5, 2019. The confirmed meeting times and agenda will be posted on the NVAC website at *http://www.hhs.gov/nvpo/nvac/meetings/index.html* as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted one week prior to the meeting at: *http://www.hhs.gov/nvpo/nvac/meetings/index.html.* Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend