information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 666(a)(5)(C) and 652(a)(7).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–13855 Filed 6–28–23; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meetings

AGENCY: Office of Head Start (OHS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Head Start Act, notice is hereby given of two tribal consultation sessions to be held between HHS/ACF OHS leadership and the leadership of tribal governments operating Head Start and Early Head Start programs. The purpose of these consultation sessions is to discuss ways to better meet the needs of American Indian and Alaska Native (AI/AN) children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. Two tribal consultations will be held as part of HHS/ACF or ACF Tribal Consultation Sessions.

DATES:

Wednesday, September 13, 2023
Tuesday, December 5, 2023

ADDRESSES:

- September 13, 2023—1–4 p.m. ET (Virtual)
- December 5, 2023—2–5 p.m. PT (Hilton Costa Mesa, 3050 Bristol Street, Costa Mesa, CA 92626)

FOR FURTHER INFORMATION CONTACT: Todd Lertjuntharangool, Regional Program Manager, Region XI/AIAN, Office of Head Start, email *Todd.Lertjuntharangool@acf.hhs.gov,* or phone (866) 763–6481. Additional information and online meeting registration will be forthcoming.

SUPPLEMENTARY INFORMATION: In accordance with section 640(l)(4) of the Head Start Act, 42 U.S.C. 9835(1)(4), ACF announces OHS Tribal Consultation Sessions for leaders of tribal governments operating Head Start and Early Head Start programs.

The agenda for the scheduled OHS Tribal Consultations reflects the statutory purposes of Head Start tribal consultations related to meeting the needs of AI/AN children and families. OHS will also highlight the progress made in addressing issues and concerns raised in the previous OHS Tribal Consultations.

The consultation sessions include elected or appointed leaders of Tribal governments and their designated representatives. Designees must have a letter from the Tribal government authorizing them to represent the Tribe. Tribal governments must submit the designee letter at least 3 days before the consultation sessions to Todd Lertjuntharangool at *Todd.Lertjuntharangool@acf.hhs.gov*. Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

Within 45 days of the consultation sessions, a detailed report of each consultation session will be available for all tribal governments receiving funds for Head Start and Early Head Start programs. Tribes can submit written testimony for the report to Todd Lertjuntharangool at *Todd.Lertjuntharangool@acf.hhs.gov* prior to each consultation session or within 30 days of each meeting. OHS will summarize oral testimony and comments from the consultation sessions in each report without attribution, along with topics of concern and recommendations.

Megan E. Steel,

ACF Certifying Officer.

[FR Doc. 2023–13793 Filed 6–28–23; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3657]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Accreditation Scheme for Conformity Assessment 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 July 31, 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 0910–0889. 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 Scheme for Conformity Assessment Program

OMB Control Number 0910–0889—Revision

Section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d) provides for the establishment of performance standards, authorizing the Accreditation Scheme for Conformity Assessment Program (ASCA Program) under section 514(d). On September 25, 2020 (85 FR 60471), we announced the

implementation of a pilot program under which testing laboratories may be accredited by ASCA-recognized accreditation bodies meeting criteria specified by FDA to assess the conformance of a device to certain FDA-recognized standards. These testing laboratories then receive ASCA Accreditation from FDA. Determinations by ASCA-accredited testing laboratories that a device conforms with an eligible standard included as part of the program are accepted by FDA for the purposes of demonstrating conformity unless FDA finds that a particular such determination shall not be so accepted.[1] The statute provides that FDA may review determinations by accredited testing laboratories, including by conducting periodic audits of such determinations or processes of accreditation bodies or testing laboratories.[2]

Following such a review, or if FDA becomes aware of information materially bearing on safety or effectiveness of a device tested by an ASCA-accredited testing laboratory, FDA may take additional measures as determined appropriate, including suspension or withdrawal of ASCA Accreditation of a testing laboratory, withdrawal of ASCA Recognition of an accreditation body, or a request for additional information regarding a specific device.[3] The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Program supports the Agency's continued efforts to use its scientific resources effectively and efficiently to protect and promote public health. FDA believes the voluntary ASCA Program may further encourage international harmonization of medical device regulation because it incorporates elements, where appropriate, from a well-established set of international conformity assessment practices and standards (*e.g.,* ISO/IEC 17000 series). The voluntary ASCA Program does not supplant or alter any other existing statutory or regulatory requirements governing the decision-making process for premarket submissions.

We are revising the information collection to reflect recent legislative changes. In accordance with amendments made to section 514 by the FDA Reauthorization Act of 2022 (FDARA),[4] and as part of the enactment of the Medical Device User Fee Amendments of 2022 (MDUFA V),[5] the ''pilot'' language and sunset clause was removed from the section, allowing FDA to conclude the pilot and continue to operate the program consistent with the amended section 514(d) of the FD&C Act. In accordance with these updates and as included in the Center for Devices and Radiological Health Proposed Guidances for Fiscal Year 2023,[6] we intend to update the applicable guidance documents.

Finally, to assist testing laboratories and accreditation bodies in submitting information to FDA, we are developing webforms for applying for ASCA Accreditation and ASCA Recognition, respectively.

Under the ASCA Program's conformity assessment scheme, ASCA-recognized accreditation bodies accredit testing laboratories using ISO/IEC 17025:2017: ''General requirements for the competence of testing and calibration laboratories'' and the ASCA program specifications associated with each eligible standard and test method included in the ASCA Program. ASCA-accredited testing laboratories may conduct testing to determine conformance of a device with at least one of the standards eligible for inclusion in the ASCA Program. When an ASCA-accredited testing laboratory conducts such testing, it provides a complete test report and an ASCA Summary Test Report to the device manufacturer. A device manufacturer who utilizes an ASCA-accredited testing laboratory to perform testing in accordance with the provisions of the ASCA Program can then include a declaration of conformity with supplemental documentation (including an ASCA Summary Test Report) as part of a premarket submission to FDA. Testing performed by an ASCA-accredited testing laboratory can be used to support a premarket submission for any device if the testing was conducted using a standard included in the ASCA Program and in accordance with the ASCA program specifications for that standard.

The ASCA Program includes participation from accreditation bodies, testing laboratories, device manufacturers, and FDA staff. Each of these entities plays a critical role in the ASCA Program to ensure that patients and healthcare providers have timely and continued access to safe, effective, and high-quality medical devices.

To participate in the ASCA Program, accreditation bodies and testing laboratories apply to FDA to demonstrate that they have the qualifications for their respective roles within the program. An application includes agreement to terms of participation. For example, a participating accreditation body or testing laboratory agrees to attend training, regularly communicate with FDA, and support periodic FDA audits. FDA will identify the scope of ASCA Recognition (for accreditation bodies) and ASCA Accreditation (for testing laboratories) for specific standards and test methods to which each participant may accredit or test as part of the ASCA Program.

During the ASCA Program, FDA generally will accept test results from ASCA-accredited testing laboratories to support conformity of a medical device to a particular standard and does not intend to review complete test reports from ASCA-accredited testing laboratories in support of a declaration of conformity submitted with a premarket submission except in certain circumstances.

Note that ASCA Accreditation is separate from any accreditation that an accreditation body may provide to a testing laboratory for purposes other than the ASCA Program.

The ASCA Program does not address specific content for a particular premarket submission. Information collections associated with premarket submissions have been previously approved.

We plan to issue draft guidance updates to the three published ASCA Pilot guidance documents[7] to improve and streamline the ASCA Program. The guidance updates are being issued to discuss the lessons learned during ASCA's pilot phase and to help

[1] *See* section 514(d)(1)(B) of the FD&C Act.

[2] *See* section 514(d)(2)(A) of the FD&C Act.

[3] *See* section 514(d)(2)(A)–(B) of the FD&C Act.

[4] *See* Public Law 117–180, section 2005.

[5] *See also* MDUFA V Commitment Letter: *https://www.fda.gov/media/158308/download*.

[6] *See* CDRH Proposed Guidances for Fiscal Year 2023, B-list: *https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2023-fy2023#b*.

[7] The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program*). Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and*). Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme*).

facilitate the transition from a pilot to a permanent program. As a result of these guidance updates, there is minimal adjustment to the burden estimate.

Respondents are accreditation bodies (ABs) and testing laboratories (TLs). In tables 1 through 3, these abbreviations are used.

In the **Federal Register** of January 19, 2023 (88 FR 3419), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Application by AB for ASCA Recognition	8	1	8	6	48
Request by AB to continue ASCA Recognition	2	1	2	6	12
Request by AB for ASCA Recognition (subsequent to withdrawal).	1	1	1	6	6
Request by AB to expand scope of ASCA Recognition	1	1	1	6	6
AB annual status report	8	1	8	3	24
AB notification of change	8	1	8	1	8
Application by TL for ASCA Accreditation	150	1	150	4	600
Request by TL to continue ASCA Accreditation	75	1	75	4	300
Request by TL for ASCA Accreditation (subsequent to withdrawal or suspension).	5	1	5	4	20
Request by TL to expand scope of ASCA Accreditation	75	1	75	4	300
TL annual status report	150	1	150	1.5	225
TL notification of change	5	1	5	1	5
Request for withdrawal or suspension of ASCA Accreditation (TLs) or request for withdrawal of ASCA Recognition (ABs).	6	1	6	0.08 (5 minutes).	1
Feedback questionnaire (ABs and TLs)	158	1	158	0.5 (30 minutes).	79
Total					1,634

[1] Totals have been rounded to the nearest hour.
[2] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
AB setup documentation standard operating procedures (SOPs) & training (one-time burden)	3	1	3	25	75
TL setup documentation SOPs & training (one-time burden)	20	1	20	25	500
AB record maintenance	8	1	8	1	8
TL record maintenance	150	1	150	1	150
Total					733

[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]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Request for Accreditation (TLs requesting accreditation from ABs).	150	1	150	0.5 (30 minutes).	75
Review/Acknowledgement of accreditation request (ABs)	8	22	176	40	7,040
Test Reports (TLs)	880	1	880	1	880
Total					7,995

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

Our estimate of eight ABs is based on the number of International Laboratory Accreditation Cooperation signatories in the U.S. economy. We estimate that approximately 150 testing labs will seek ASCA Accreditation. Our estimate of Test Reports is based on the number of premarket submissions we expect per year with testing from an ASCA-accredited testing laboratory.

Our estimates for the number of respondents and average burden per

response, recordkeeping, and disclosure are based on our experience with the pilot program.

Our estimated burden for the information collection reflects an overall decrease of 3,129 hours and an increase of 94 responses/records. We attribute this adjustment to a decrease in the one-time burden for accreditation bodies and testing laboratories training and SOPs because much of this activity was completed during the pilot. In addition, there is an increase in the annual responses/records because there is an increase in renewal requests (by accreditation bodies to continue ASCA Recognition and by testing laboratories to continue ASCA Accreditation) since the pilot program was initiated.

Dated: June 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13860 Filed 6–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0366]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Advisory Committee Regulations

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 July 31, 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 0910–0833. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

FDA Advisory Committee Regulations

OMB Control No. 0910–0833—Revision

This information collection helps support implementation of FDA regulations found in part 14 (21 CFR part 14). These regulations govern procedures applicable to presenting information and views before an FDA advisory committee in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 and 3, Pub. L. 92–463). FACA is designed to assure that Congress and the public are kept informed with respect to the purpose, membership, and activities of advisory committees. It does not specify the manner in which advisory committee members and staff must be appointed.

Public advisory committee regulations in part 14 set forth requirements governing the administrative procedures to follow for the operation of advisory committees. Agency regulations in part 14, subpart A (§§ 14.1 through 14.15) identify scope of coverage, applicable definitions, and establish general provisions. The regulations in part 14, subpart B (§§ 14.20 through 14.39) set forth content and format requirements along with required schedules for submission of information. The regulations in part 14 subparts C, D, and E (§§ 14.40 through 14.95) set forth requirements governing advisory committee establishment, recordkeeping, and maintenance, respectively.

FDA will also require that nominees to serve on advisory committees submit a consent form authorizing FDA to post, without removing or redacting any information, to FDA's public website (*http://www.fda.gov/AdvisoryCommittees*) the curriculum vitae (CV) submitted as part of their nomination materials if the nominee is selected to serve on an advisory committee. The consent form requires that the nominee affirm that the CV does not include any confidential information, including information pertaining to third parties, that the nominee is not permitted to disclose. A nominee will be required to submit a signed consent form as a part of the nomination package for the nomination to be considered complete.

All nominations for new advisory committee members will be required to be submitted through FDA's website at *http://accessdata.test.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm,* or any successor system, and the submission will be required to be accompanied by the consent form, on or after the date of OMB approval for this information collection. Although we are developing collection instruments, as communicated on our website, respondents may submit information to: Advisory Committee Oversight and Management Staff, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993, 800–741–8138 or 301–443–0572.

In the **Federal Register** of February 13, 2023 (88 FR 9294), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four comments were received but were not responsive to the information collection topics solicited under the PRA. On our own initiative, we are clarifying the scope of coverage for the information collections.

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