• NABP agreement or policies for voluntary and involuntary termination of the HIT AO program.

• NABP's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

IV. Collection of Information Requirements

This document does not impose information collection and 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*).

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 14, 2020.

Evell J. Barco Holland,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–08990 Filed 4–27–20; 8:45 am]

BILLING CODE 4120–01–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 Pilot 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: Fax written comments on the collection of information by May 28, 2020.

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 title of this information collection is ''Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.'' 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.

Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

OMB Control Number 0910–NEW

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d(d)) by adding a new subsection (d) entitled ''Pilot Accreditation Scheme for Conformity Assessment.[1] Section 514(d) of the FD&C Act requires FDA to establish a pilot program under which testing laboratories may be accredited, by accreditation bodies meeting criteria specified by FDA, to assess the conformance of a device within certain FDA-recognized standards. Determinations by testing laboratories so accredited that a device conforms with an eligible standard included as part of the ASCA Pilot Program shall be accepted by FDA for the purposes of demonstrating such conformity, unless FDA finds that a particular such determination shall not be so accepted.[2]

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.[3] Following such a review, or if FDA becomes aware of information materially bearing on safety or effectiveness of a device assessed by an accredited testing laboratory, FDA may take additional measures as determined appropriate, including suspension or withdrawal of ASCA Accreditation of a testing laboratory or a request for additional information regarding a specific device.[4]

FDA intends to issue guidance regarding the goals and implementation of the voluntary Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program (hereafter referred to as the ASCA Pilot) in accordance with amendments made to section 514 of the FD&C Act[5] by FDARA, and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV).[6]

The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Pilot 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 Pilot 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 Pilot does not supplant or alter any other existing statutory or regulatory requirements governing the decision-

[1] See Pub. L. 115–52, section 205.

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

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

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

[5] See section 514(d)(3)(B) of the FD&C Act.

[6] See also MDUFA IV Commitment Letter: *https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf.*

making process for premarket submissions.

Under the ASCA Pilot's conformity assessment scheme, recognized accreditation bodies accredit testing laboratories using ASCA program specifications associated with each eligible standard and ISO/IEC 17025:2017: *General requirements for the competence of testing and calibration laboratories.* 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 Pilot. When an ASCA-accredited testing laboratory conducts testing under the ASCA Pilot, it provides both a complete and summary test report to the device manufacturer. Device manufacturers may choose to use a testing laboratory participating in the ASCA Pilot to conduct testing for premarket submissions to FDA. A device manufacturer who uses an ASCA-accredited testing laboratory to perform testing in accordance with the provisions of the ASCA Pilot then includes a declaration of conformity with supplemental documentation (*e.g.,* 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 eligible for inclusion in the ASCA Pilot and in accordance with the ASCA program specifications for that standard.

To participate in the ASCA Pilot, accreditation bodies apply to FDA for recognition. An application includes demonstration that they have the qualifications for recognition and agreement to terms of participation. For example, a recognized accreditation body agrees to attend training, regularly communicate with FDA, and support periodic FDA audits. When FDA grants recognition, we will identify the scope of recognition of specific standards and test methods to which the accreditation body may accredit testing laboratories as part of the ASCA Pilot.

To participate in the ASCA Pilot, testing laboratories apply to FDA for ASCA Accreditation. An application includes demonstration that they have the qualifications for ASCA Accreditation and agreement to terms of participation. For example, an ASCA-accredited testing laboratory agrees to attend training, regularly communicate with FDA, and support periodic FDA audits. When FDA grants ASCA Accreditation, we will identify the scope of ASCA Accreditation of specific standard and test methods to which the testing laboratory may conduct testing as part of the ASCA Pilot.

During the ASCA Pilot, FDA generally will accept determinations from ASCA-accredited testing laboratories that a medical device is in conformity with the specified testing 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 Pilot. FDA's decision to recognize the accreditation for purposes of the ASCA Pilot is separate and distinct from any independent decision by the accreditation body with respect to a testing laboratory for purposes outside of the ASCA Pilot.

The ASCA Pilot does not address specific content for a particular premarket submission. Collections of information found in FDA regulations and guidance, associated with premarket submissions, have been previously approved as follows. The collections of information in 21 CFR part 807, subpart E (premarket notification) have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts A through E (premarket approval) have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H (humanitarian device exemption) have been approved under OMB control number 0910–0332; the collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 312 (investigational new drug application) have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 601 (biologics license application) have been approved under OMB control number 0910–0338.

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

In the **Federal Register** of September 5, 2019 (84 FR 46737), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment on the 60-day notice, but it was not related to the information collection or the ASCA Pilot Program. We also considered comments received on the draft guidance entitled ''The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program'' (see 84 FR 49741, September 23, 2019). We have made no changes to the burden estimate as a result of the comments. However, as a result of comments on the draft guidance and for clarity, we have updated certain terminology used to describe the ASCA Pilot.

FDA estimates the burden of this collection of information 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 (hours)	Total hours [2]
Application by AB for ASCA recognition	8	1	8	6	48
Request by AB to continue recognition	1	1	1	6	6
Request by AB for recognition (subsequent to withdrawal)	1	1	1	6	6
Request by AB to expand scope of 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	15	1	15	4	60
Request by TL for ASCA Accreditation (subsequent to withdrawal or suspension)	5	1	5	4	20

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours [2]
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 recognition (ABs)	6	1	6	0.08 (5 minutes)	1
Pilot feedback questionnaire (ABs and TLs)	158	1	158	0.5 (30 minutes)	79
Total					1,388

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
AB setup documentation (standard operating procedures (SOPs)) and training (one-time burden)	8	1	8	25	200
TL setup documentation (SOPs) and training (one-time burden)	150	1	150	25	3,750
AB record maintenance	8	1	8	1	8
TL record maintenance	150	1	150	1	150
Total					4,108

[1] There are no capital costs or operating and maintenance costs associated with the 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 (hours)	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 Report (TLs)	880	1	880	1	880
Total					7,995

[1] There are no capital costs or operating and maintenance costs associated with the 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 laboratories will seek 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 as part of the ASCA Pilot Program.

Our estimates for the average burden per response, recordkeeping, and disclosure are based on the burden for similar programs.

Dated: April 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–08989 Filed 4–27–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: The National Health Service Corps and Nurse Corps Interest Capture Form, OMB No. 0915–0337—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.