



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-7130]

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@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--Reinstatement

The FDA Reauthorization Act of 2017 (FDARA), enacted as part of the Medical Device User Fee Amendments of 2017 (MDUFA IV), amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding Section 514(d). Section 514(d) directed FDA to establish a pilot program under which testing laboratories may be accredited by accreditation bodies meeting criteria specified by FDA to assess whether a device conforms with certain FDA-recognized consensus standards. The FDA User Fee Reauthorization Act of 2022 (FUFRA), enacted as part of the Medical Device User Fee Amendments of 2022 (MDUFA V), subsequently directed FDA to conclude the pilot phase and continue the Accreditation Scheme for Conformity Assessment (ASCA) as an ongoing program.

FDA generally accepts determinations by ASCA-accredited testing laboratories that a device conforms with an eligible standard unless FDA determines that a particular conformity determination should not be accepted.

The statute provides that FDA may review determinations made by accredited testing laboratories, including by conducting periodic audits of such determinations or reviewing the processes of accreditation bodies or testing laboratories.

Following such a review, or if FDA becomes aware of information materially bearing on safety or effectiveness of a device assessed by an ASCA-accredited testing laboratory, FDA may take additional measures as determined appropriate. Such measures may include suspension or withdrawal of a testing laboratory's ASCA Accreditation, withdrawal of an accreditation body's ASCA Recognition, or a request for additional information regarding a specific device.

FDA issued the final guidance "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program" in September 2020 to discuss the goals and implementation of the voluntary ASCA Pilot Program. In September 2024, FDA issued three draft guidance documents

intended to update the ASCA Program based on lessons learned during the pilot phase and support its continued operation as an ongoing program.

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.

Under the ASCA Program's conformity assessment scheme, ASCA-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 Program. When an ASCA-accredited testing laboratory conducts such testing, it may provide a complete 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 a 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 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 request ASCA Recognition from FDA. Testing laboratories first obtain accreditation from an ASCA-recognized accreditation body and then request ASCA Accreditation from FDA. Each application includes an agreement to comply with the applicable 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 recognizes qualified applicants as participants. In its recognition, FDA will identify the scope of recognition of specific standards and test methods to which each participant may accredit or test as part of the ASCA Program.

After recognizing a testing laboratory as a participant in the ASCA Program, FDA will generally grant the testing laboratory ASCA Accreditation. During the ASCA Program, 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. The ASCA Declaration of Conformity, including any ASCA-specific content required therein, is submitted as part of a premarket submission and is therefore not covered under this ICR.

ASCA Accreditation is separate from any accreditation that an accreditation body may provide to a testing laboratory for purposes other than the ASCA Program. FDA's decision to recognize the accreditation for purposes of the ASCA Program is separate and distinct from any independent decision by the accreditation body with respect to a testing laboratory for purposes outside of the ASCA Program.

The ASCA Program does not address all specific content for a particular premarket submission. Specifically, the ASCA Declaration of Conformity and its ASCA-specific content

are submitted in connection with a premarket submission and are subject to the information collection requirements applicable to premarket submissions, which have been previously approved. Information collections associated with premarket submissions are therefore not included in this ICR.

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

In the *Federal Register* of July 17, 2026 (91 FR 44854) FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received. Both comments were determined to be PRA-related.

The first comment was submitted by an ASCA-recognized accreditation body. The commentor commented on the extension process for currently recognized accreditation bodies under Section X, Subsection C (Extension of ASCA Recognition) of the ASCA Pilot Program Final Guidance (September 25, 2020). The commentor recommended that FDA streamline the process by limiting submission requirements to information directly relevant to the requested extension and any information that has materially changed since the accreditation body's most recent recognition or renewal, rather than requiring resubmission of documentation FDA has recently reviewed.

FDA appreciates the commentor's comment and acknowledges the concern that the current extension process may generate duplicative administrative burden for accreditation bodies and FDA staff. FDA is currently preparing the final version of the ASCA Program Guidance (draft September 20, 2024) that will replace the ASCA Pilot Program Guidance of September 25, 2020, which we believe will address concerns like these. FDA will continue to evaluate opportunities to reduce unnecessary burden while preserving the integrity of the ASCA Program's oversight framework.

The second comment was received from a patient, the commenter addressed two PRA-related topics: the practical utility of the information collected, and three (3) ways to enhance its quality, utility, and clarity. On practical utility, the commenter observed that the collection captures scopes only within the program's existing two standards families and therefore produces no data on where accredited testing would be most useful next. On quality and clarity, the commenter recommended adding two items to the existing feedback questionnaire: (1) ask respondents which FDA-recognized consensus standards or test methods outside the current ASCA categories they would use an accredited laboratory for if the program were extended; and (2) ask respondents whether the information generated under the program is available to and usable by a clinician or patient reviewing a device after implantation. The commenter also suggested that audit outcomes and the basis for withdrawal of ASCA accreditation be captured in the collection in a form that can be counted and compared.

FDA appreciates the commenter's observations regarding the utility and quality of the ASCA Program information collection. FDA notes that the PRA burden estimates for the ASCA Program do not represent an existing or ongoing questionnaire. Rather, the estimated burden reflects: (a) the time accreditation bodies and testing laboratories spend applying to and maintaining their status in the ASCA Program; and (b) the time testing laboratories spend completing the summary test report format for testing conducted under the program.

Regarding the commenter's observations on program scope, FDA notes that the ASCA Program launched as a pilot, which limited the number of standards eligible for inclusion. The program transitioned from a pilot to an ongoing program in 2023, and since that time, FDA has held workshops and engaged regularly with program participants on the topic of expanding the program's scope. Expansion of the standards contained in the ASCA Program is an ongoing priority for FDA.

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

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Request by AB to continue <i>ASCA Recognition</i>	2	1	2	6	12
Request by AB for <i>ASCA Recognition</i> (subsequent to withdrawal)	1	1	1	6	6
Request by AB to expand scope of <i>ASCA Recognition</i>	1	1	1	6	6
AB annual status report	5	1	5	3	15
AB notification of change	5	1	5	1	5
Application by TL for <i>ASCA Accreditation</i>	50	1	50	4	200
Request by TL to continue <i>ASCA Accreditation</i>	75	1	75	1	75
Request by TL for <i>ASCA Accreditation</i> (subsequent to withdrawal or suspension)	5	1	5	4	20
Request by TL to expand scope of <i>ASCA Accreditation</i>	75	1	75	4	300
TL annual status report	100	1	100	1.5	150
TL notification of change	5	1	5	1	5
Voluntary Request for withdrawal or suspension of <i>ASCA Accreditation</i> (TLs) or request for withdrawal of <i>ASCA Recognition</i> (ABs)	6	1	6	0.08 (5 mins.)	1
TOTAL					795

Table 2.--Estimated Annual Recordkeeping Burden

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
AB setup documentation (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			181		733

Table 3.--Estimated Annual Third-Party Disclosure Burden

Activity	No. of Respondents	No. 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			1,206		7,995

We have adjusted our burden estimate to reflect maturation of the ASCA Program, which has resulted in a decrease from the currently approved burden. The overall net decrease of

approximately 829 burden hours is an adjustment, not a program change. The draft guidance updates issued in September 2024 contribute minimally to these adjustments. There are no changes to the estimated recordkeeping or third-party disclosure burdens.

The decrease includes 48 hours from removing initial applications for ASCA Recognition; 400 hours from reducing anticipated ASCA Accreditation applications from 150 to 50 respondents; 225 hours from reducing the estimated time for TL continuation requests from 4 hours to 1 hour; 12 hours from reducing AB annual status reports and notifications of change from 8 to 5 respondents; 75 hours from reducing for TL annual status reports from 225 to 150 hours, and 79 hours from omitting feedback questionnaires conducted during the pilot.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-21712 Filed: 10/22/2026 8:45 am; Publication Date: 10/23/2026]