or we) implementation of its Voluntary Improvement Program (VIP). Included among the strategic priorities of our Center for Devices and Radiological Health (CDRH) is promoting a culture of quality and organizational excellence. As communicated on our website at *https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/voluntary-medical-device-manufacturing-and-product-quality-pilot-program,* we conducted a pilot project pertaining to voluntary medical device manufacturing and product quality and have incorporated some of the successes and learnings into the VIP. The VIP oversees third-party appraisers who evaluate industry participants. The VIP is facilitated by the Medical Device Innovation Consortium (MDIC), a public-private partnership that evaluates the capability and performance of a medical device manufacturer's practices using third-party appraisals, and is intended to guide improvement to enhance the quality of devices. As part of the VIP process, FDA receives information about participating device manufacturers' capability and performance for activities covered in third-party appraisals.

The guidance document entitled, ''*Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program,*'' communicates our policy regarding participation in the VIP. Only eligible manufacturers of medical devices regulated by CDRH whose marketing applications are reviewed under the applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (including sections 510(k), 513, 515, and 520) may participate in the VIP. The guidance document was developed and issued consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. The guidance document includes instruction to respondents regarding eligibility, FDA engagement with participants, submission criteria, and withdrawal or removal from the program. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Recommended information collection activity: *Fostering medical device improvement: FDA activities and engagement with the Voluntary Improvement Program*	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Site manufacturer application	1	300	300	0.08	24
Aggregate data reporting	1	4	4	8	32
Summary of site appraisal	1	300	300	20	6,000
Total					6,056

Our estimated burden for the information collection reflects an overall decrease of 2,009 hours and a corresponding decrease of 200 responses. We attribute this adjustment based on our device registration and listing data and informal feedback from stakeholders.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14436 Filed 7–16–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA–2026–N–7130]

Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation Scheme for Conformity Assessment Program

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 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Accreditation Scheme for Conformity Assessment (ASCA) Program.

DATES: Either electronic or written comments on the collection of information must be submitted by September 15, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 15, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for

information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–7130 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation Scheme for Conformity Assessment Program.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension/reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Accreditation Scheme for Conformity Assessment Program

OMB Control Number 0910–0889—Extension

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 ''Accreditation Scheme for Conformity Assessment.''

Section 514(d) of the FD&C Act required 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 accredited testing laboratories that a device conforms with an eligible standard included as part of the ASCA 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.

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.

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 accreditation of a testing laboratory or a request for additional information regarding a specific device.

FDA issued the final guidance ''The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program'' (*https://www.fda.gov/media/130901/download*) to discuss the goals and implementation of the voluntary ASCA Pilot Program (hereafter referred to as the ASCA Program in accordance with amendments made to section 514 of the FD&C Act by FDARA, and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV)).

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, 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 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 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.

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. 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 specific content for a particular premarket submission. Information collections associated with premarket submissions have been previously approved.

FDA plans to issue draft guidance updates to the three published ASCA Pilot guidance documents 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 also 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Avg. burden per response	Total hours
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	5	1	5	3	15
AB notification of change	5	1	5	1	5
Application by TL for *ASCA Accreditation*	50	1	50	4	200
Request by TL to continue *ASCA Accreditation*	75	1	75	1	75
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	100	1	150	1.5	225
TL notification of change	5	1	5	1	5
Voluntary Request for withdrawal or suspension of *ASCA Accreditation* (TLs) or request for withdrawal of *ASCA Recognition* (ABs).	6	1	6	0.08 (5 mins.)	1
Feedback questionnaire (DMs, ABs and TLs)	158	1	158	0.5 (30 mins.)	79
Total					949

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

Activity	Number of recordkeepers	Number 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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
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	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			1,206		7,995

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. The overall net decrease of approximately 685 burden hours is an adjustment, not a program change. It reflects the maturation of the ASCA Program from a pilot to a permanent program: fewer accreditation bodies (Abs) are expected to submit initial recognition applications, and fewer testing laboratories (TLs) are seeking initial accreditation as the participant base has already been largely established. The average burden per response for certain TL activities was also reduced to reflect efficiencies gained through experience with the program. FDA notes that guidance updates being issued to improve and streamline the program contribute minimally to these adjustments. Application by Abs for ASCA Recognition was removed from the FY26 table, reflecting that initial AB applications have already been submitted; the previously reported burden included 8 ABs × 6 hrs = 48 hours for this activity. Request by TLs for ASCA Accreditation (initial applications) decreased from 150 respondents to 50, reducing hours from 600 to 100 (−500 hours), as the program is now more mature and fewer new TLs are expected to apply for initial accreditation. Request by TL to continue ASCA Accreditation average burden per response decreased from 4 hours to 1 hour (−225 hours net impact), reflecting program streamlining. AB annual status report respondents decreased from 8 to 5; AB notification of change respondents decreased from 8 to 5. Feedback questionnaire now explicitly includes Device Manufacturers (DMs) as respondents in addition to ABs and TLs, though the respondent count (158) and hours (79) remain unchanged.

There is no change in recordkeeping burden. Estimates for AB and TL setup documentation/training (one-time burden) and ongoing record maintenance remain identical. There is no change in third-party disclosure burden. Estimates for TL requests for accreditation from ABs, AB review/acknowledgment of accreditation requests, and Test Reports remain identical.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14441 Filed 7–16–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7338]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary National Retail Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Voluntary National Retail Food Regulatory Program Standards.

DATES: Either electronic or written comments on the collection of information must be submitted by September 15, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 15, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically,