Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: January 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00926 Filed 1–18–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3657]

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, Agency, or we) 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 information collection associated with the Accreditation Scheme for Conformity Assessment (ASCA) Program.

DATES: Either electronic or written comments on the collection of information must be submitted by March 20, 2023.

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 March 20, 2023. 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–2019–N–3657 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 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: 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 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 [1] to improve

[1] The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program | FDA (*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 | FDA (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and*).

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 [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
Pilot 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.

Biocompatibility Testing of Medical Devices—Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program | FDA (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme*).

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 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 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 (Request by AB to continue *ASCA Recognition* and Request by TL to continue *ASCA Accreditation*) since the pilot program was initiated.

Dated: January 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00973 Filed 1–18–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice.

SUMMARY: In accordance with the Public Health Service Act, and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: Thursday, February 9, 2023, from 9:30 a.m. to 3 p.m. Eastern Time (ET) and Friday, February 10, 2023, from 9:30 a.m. to 2 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required. Please visit the ACHDNC website for information on registration: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html* by the deadline of 12 p.m. ET on February 8, 2023. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301–443–0721; or *ACHDNC@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel (RUSP), following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the February 9–10, 2023, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

(1) Presentation of the final evidence-based review report on the Krabbe disease condition nomination for possible inclusion on the RUSP. Following this report presentation, the ACHDNC expects to vote on whether to recommend to the Secretary adding Krabbe Disease to the RUSP;

(2) An update by the ACHDNC Prioritization and Capacity workgroup;

(3) A possible presentation from the Center for Disease Control and Prevention's Enhancing Data Driven Disease Detection in Newborns Project;

(4) A potential update on the HRSA-funded Newborn Screening Interoperability Programs;

(5) A presentation on the Blueprint for Change, which outlines an agenda for advancing the system of services for children and youth with special health care needs (see *https://mchb.hrsa.gov/programs-impact/focus-areas/children-youth-special-health-care-needs-cyshcn/blueprint-change*);

(6) Workgroup updates; and

(7) A potential update on the Duchenne muscular dystrophy condition nomination and a potential vote on whether to move it forward to full evidence-based review, which, depending on the strength of the evidence, could lead to a future recommendation to add this condition to the RUSP.

The agenda for this meeting includes a potential vote to recommend a nominated condition (Krabbe Disease) be added by the Secretary to the RUSP. In addition, as noted in the agenda items, the Committee may hold a vote on whether or not to recommend a nominated condition (Duchenne muscular dystrophy) to full evidence-based review, which may lead to a recommendation to add or not add this condition to the RUSP at a future time.

Agenda items are subject to change as priorities dictate. Information about the ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website.

Members of the public also will have the opportunity to provide comments on any or all of the above agenda items. Public participants may request to provide general oral comments and may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Subject to change: members of the public registered to submit oral public comments on Krabbe Disease are tentatively scheduled to provide their statements on Thursday, February 9, 2023. Members of the public registered to provide oral public comments on all other newborn screening related topics are tentatively scheduled to provide their statements on Friday, February 10, 2023. Requests to provide a written statement or make oral comments to the ACHDNC must be submitted via the registration website by 12 p.m. ET on