



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-3805]

The Accreditation Scheme for Conformity Assessment Pilot Program; Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.” The Pilot Accreditation Scheme for Conformity Assessment Program (hereafter referred to as the ASCA Pilot) is authorized under the Federal Food, Drug, and Cosmetic Act (FD&C Act). In accordance with amendments made to the FD&C Act by the FDA Reauthorization Act of 2017 (FDARA) and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV), FDA was directed to issue a draft guidance regarding the goals and implementation of the ASCA Pilot. 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 to protect and promote public health by simplifying certain aspects of premarket review, thereby reducing burdens on the Agency for individual submissions. 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-making process for premarket submissions. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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-D-3805 for “The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program; Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff.” Received comments 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.

- 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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program; Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff” to the Office of Policy, Guidance and Policy Development, Center for

Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erin Cutts, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5554, Silver Spring, MD 20993-0002, 301-796-6307; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Reauthorization Act of 2017 (FDARA) amended section 514 of the FD&C Act (21 U.S.C. 360d) by adding a new subsection (d) with the title “Pilot Accreditation Scheme for Conformity Assessment” (see Pub. L. 115-52, section 205). The new section 514(d) 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 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.

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.

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 such testing, it may provide a complete test report to the device manufacturer containing the elements listed in the ASCA program specifications. A device manufacturer who utilizes an ASCA-accredited testing laboratory to perform testing in accordance with the provisions of the ASCA Pilot can then include a declaration of conformity with supplemental documentation (including a summary test report) as part of a premarket submission to FDA.

FDA held a public workshop entitled "Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards" on May 22-23, 2018¹, to obtain input and recommendations from stakeholders about the ASCA Pilot, including its goals and scope as well as a suitable framework and procedures to facilitate implementation. The ASCA Pilot is predicated on the processes and policies outlined in this guidance regarding

¹ Federal Register Notice: <https://www.federalregister.gov/documents/2018/01/16/2018-00551/accreditation-scheme-for-conformity-assessment-of-medical-devices-to-food-and-drug>.

demonstration of competence and program participation by accreditation bodies and testing laboratories.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the "Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances> [or](#) <https://www.regulations.gov>. Persons unable to download an electronic copy of "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program; Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 17037 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

In the *Federal Register* of September 5, 2019 (84 FR 46737), FDA requested public comment on the collections of information associated with the ASCA Pilot. The proposed information collection and our burden estimate is substantially the same, and is meant to encompass, the information collections proposed in the draft guidance.

In addition, this draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR Part or Guidance	Topic	OMB Control No.
807, subpart E	Premarket Notification	0910-0120
814, subparts A through E	Premarket Approval	0910-0231
814, subpart H	Humanitarian Device Exemption	0910-0332
812	Investigational Device Exemption	0910-0078
“De Novo Classification Process (Evaluation of Automatic Class III Designation)”	De Novo Classification Process	0910-0844
312	Investigational New Drug Application	0910-0014
601	Biologics License Application	0910-0338

Dated: September 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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