TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Total	.....	.....	.....	.....	23,100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this information collection has not changed since the last OMB approval.

This document also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The collections of information found in §§ 821.2(b), 821.25(e), and 821.30(e) have been approved under OMB control number 0910–0191.

Dated: January 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00568 Filed 1–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6877]

Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Accreditation Scheme for Conformity Assessment of Medical Devices to FDA-Recognized Standards.'' The purpose of the workshop is to present a draft design of the Accreditation Scheme for Conformity Assessment (ASCA) pilot program. The workshop is intended to discuss and obtain input and recommendations from stakeholders on the draft accreditation scheme, including its goals and scope, a suitable framework and procedures, and requirements to facilitate implementation of an eventual pilot program. The overarching objectives of the ASCA pilot program are to streamline the standards conformity assessment of medical devices and to improve consistency and predictability in the premarket review process where certain FDA recognized standards are used.

DATES: The public workshop will be held on May 22 and 23, 2018, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by June 29, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 29, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of June 29, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2017–N–6877 for ''Accreditation Scheme for Conformity Assessment of Medical Devices to FDA-Recognized Standards; Public Workshop; Request for Comments.'' 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.

- 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.

FOR FURTHER INFORMATION CONTACT: Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5514, Silver Spring, MD 20993–0002, 301–796–6287, *CDRHStandardsStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

As part of the Medical Device User Fee Amendments of 2017 (MDUFA IV), FDA and industry agreed to establish a Pilot Accreditation Scheme for Conformity Assessment (ASCA) Program for recognizing accredited testing laboratories that evaluate medical devices per certain FDA-recognized standards. Section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d) was amended by adding a new subsection (d) with the title ''Pilot Accreditation Scheme for Conformity Assessment,'' under the FDA Reauthorization Act of 2017 (FDARA). The new section 514(d) authorizes FDA to establish a pilot program under which FDA may select accreditation bodies that can accredit testing laboratories meeting FDA-specified criteria to assess conformance of medical devices to certain FDA-recognized consensus standards under the ASCA pilot program. The goal of this pilot program is to streamline the standards conformity assessment of medical devices during the premarket review process. The objectives of the ASCA pilot include improved consistency and predictability in the premarket review process where certain FDA recognized standards are used.

Traditionally, under section 514(c) of the FD&C Act, FDA has been accepting a manufacturer's self-declaration of conformity to an FDA-recognized consensus standard as part of its premarket submission. Since medical devices are increasingly complex and involve high risks to the patients, such self-declaration of conformity is not always sufficient to guarantee safety and performance, especially when deviations from the standard have been introduced. In addition, testing performed by the independent laboratories or the manufacturers themselves to support the self-declaration of conformity varies depending on the standard being used. As a result, reviewers sometimes need to request and review test reports to ensure requirements of the standard have been met. The ASCA pilot program is designed to address such issues through improved quality and increased confidence in the testing labs to achieve a least burdensome and streamlined regulatory process.

The purpose of this public workshop is to present a draft design of the ASCA scheme. FDA intends to discuss and obtain input and recommendations from stakeholders on the draft scheme, including its goals and scope, its framework and procedures, and requirements as required per FDARA. Public input and feedback gained through this workshop are also intended to aid in the development of a draft ASCA guidance, which is another MDUFA IV commitment.

II. Topics for Discussion at the Public Workshop

This public workshop will consist of both plenary presentations and breakout sessions. A keynote presentation is planned to provide high-level background information about standards use and standards conformity assessment (CA) in medical device regulatory processes, major existing CA programs, and significance of and challenges to national and international harmonization in CA. FDA will present background information about the proposed ASCA pilot program, its objectives and plans, what issues it aims to resolve and how. Following the plenary presentations, multiple breakout sessions will be convened. Each breakout session is designed to focus on a major ASCA-related topic. The topics to be discussed include:

- Performance metrics to measure the success and impact of the ASCA
- Additional requirements for accrediting bodies beyond the standard (ISO/IEC 17011:2017 Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies, available at *https://www.iso.org/standard/67198.html*) and for testing organizations beyond the standard (ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories, available at *https://www.iso.org/standard/66912.html*)
- Criteria for selection of pilot standards for ASCA
- Roles that testing organizations can play for ASCA

A detailed agenda will be posted on the following website in advance of the workshop: *https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm;* select this event from the list of items provided. The overarching objectives of the ASCA pilot program are to streamline the standards conformity assessment of medical devices, and improve consistency and predictability in the premarket review process where certain FDA recognized standards are used.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar (*https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*) and select this event from the list of items provided. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by May 14, 2018, 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993–0002, 301–796–5661, or email: *Susan.Monahan@fda.hhs.gov,* no later than May 8, 2018.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by May 16, 2018, midnight Eastern Time. All requests to make oral presentations must be received by the close of registration on May 14, 2018, 4 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to Scott Colburn (see **FOR FURTHER INFORMATION CONTACT**) no later than May 18, 2018, midnight Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. The webcast link will be available on the registration web page after May 14, 2018. Please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar (*https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*) and select this event from the list of items provided. Organizations are requested to register all participants, but to view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.*

Dated: January 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00551 Filed 1–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. During the January meeting, the Research Subcommittee will be taking charge of the theme, focusing on the process from targets to treatments. The Council will hear speakers on the preclinical pipeline, the clinical trial pipeline, and the industry perspective. The meeting will also include discussion of a driver diagram to guide the Council's future work, updates and a report from the October Care Summit, and federal workgroup updates.

DATES: The meeting will be held on January 26, 2018 from 9:00 a.m. to 5:00 p.m. EDT.

ADDRESSES: The meeting will be held in Room 800 in the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

Comments: Time is allocated in the afternoon on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Rohini Khillan, OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT:

Rohini Khillan (202) 690–5932, *rohini.khillan@hhs.gov.* Note: Seating may be limited. Those wishing to attend the meeting must send an email to *napa@hhs.gov* and put ''January 26 Meeting Attendance'' in the Subject line by Tuesday, January 16, so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: During the January meeting, the Research Subcommittee will be taking charge of the theme, focusing on the process from targets to treatments. The Council will hear speakers on the preclinical pipeline, the clinical trial pipeline, and the industry perspective. The meeting will also include discussion of a driver diagram to guide the Council's future work, updates and a report from the October Care Summit, and federal workgroup updates.

Procedure and Agenda: This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. The meeting will also be webcast at *www.hhs.gov/live.*

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: January 9, 2018.

John R. Graham,

Acting Assistant Secretary for Planning and Evaluation.

[FR Doc. 2018–00480 Filed 1–12–18; 8:45 am]

BILLING CODE 4150–05–P