consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DermatologicandOphthalmicDrugsAdvisoryCommittee/ucm094782.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: *October 7, 2016.*

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–24816 Filed 10–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2483]

Software as a Medical Device: Clinical Evaluation; International Medical Device Regulators Forum; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled ''Software as a Medical Device (SaMD): Clinical Evaluation.'' The draft guidance was prepared under the auspices of the International Medical Device Regulators Forum (IMDRF), formerly the Global Harmonization Task Force. The draft guidance pertains to the conduct of clinical evaluation of Software as a Medical Device (SaMD) and focuses on the general principles of clinical evaluation, which includes establishing the scientific validity, clinical performance, and analytical validity for a SaMD. The draft guidance is intended to provide globally harmonized principles of when and what type of clinical evaluation is appropriate based on the risk of the SaMD. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 13, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–2483 for ''Software as a Medical Device (SaMD): Clinical Evaluation.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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 ''Software as a Medical Device (SaMD): Clinical Evaluation'' to the Office of the Center Director, 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. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT: *Regarding the draft guidance:* Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993–0002, 301–796–5528.

Regarding the IMDRF: Melissa A. Torres, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5432, Silver Spring, MD 20993–0002, 301–796–5576.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. One of the goals of global harmonization is to identify and then reduce differences in regulatory policies among regulatory agencies. IMDRF seeks to advance international harmonization or convergence of medical device regulation.

IMDRF was organized to provide an opportunity for global harmonization initiatives to be developed with input from both regulatory and industry representatives. The current members of the Management Committee of the IMDRF are regulatory officials from Australia (Therapeutic Goods Administration), Brazil (National Health Surveillance Agency), Canada (Health Canada), China (China Food and Drug Administration), European Union (European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and Small and Medium-sized Enterprises), Japan (Pharmaceuticals and Medical Devices Agency and the Ministry of Health, Labour and Welfare), Russia (Ministry of Healthcare), and the United States (U.S. FDA). The World Health Organization and the Asia-Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee are Official Observers. The Asian Harmonization Working Party and the Pan American Health Organization are IMDRF Affiliate Organizations.

In September 2016, the IMDRF Management Committee endorsed the draft guidance entitled ''Software as a Medical Device (SaMD): Clinical Evaluation'' and agreed that the guidance should be made available for public comment. The IMDRF SaMD Working Group (WG) includes representatives from the IMDRF members, as well as members from the Medical Device Regulatory Authorities and Regional Harmonization Initiatives from around the world. The draft guidance is the product of the IMDRF SaMD WG. Comments about this draft will be considered by FDA and the IMDRF SaMD WG.

We welcome comments on all aspects of the draft guidance as well as the following specific issues:

1. Does the document address the intention captured in the introduction/scope or vice versa?

2. Does the document appropriately translate and apply current clinical vocabulary for SaMD?

3. Are there other types of SaMD beyond those intended for non-diagnostic, diagnostic and therapeutic purposes that should be highlighted/considered in the document?

4. Does the document adequately address the relevant clinical evaluation methods and processes for SaMD to generate clinical evidence?

5. Are there other appropriate methods for generating clinical evaluation evidence that are relevant for SaMD beyond those described in the document?

6. Are the recommendations identified in section 7.2 related to the ''importance of clinical evidence and expectations'' appropriate as outlined for the different SaMD categories?

7. Are the recommendations identified in section 7.3 related to the ''importance of independent review'' appropriate as outlined for the different SaMD categories?

8. Given the uniqueness of SaMD and the proposed framework—is there any impact on currently regulated devices or any possible adverse consequences?

The draft guidance and the IMDRF comment page are available at *http://www.imdrf.org/consultations/consultations.asp#current.*

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 ''Software as a Medical Device (SaMD): Clinical Evaluation.'' 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.

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 *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Software as a Medical Device (SaMD): Clinical Evaluation'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16039 to identify the guidance you are requesting.

Dated: October 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24805 Filed 10–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Advisory Committee; Antimicrobial Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Antimicrobial Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Antimicrobial Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until October 7, 2018.

DATES: Authority for the Antimicrobial Drugs Advisory Committee will expire on October 7, 2016, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Lauren Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *AMDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the