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FOR FURTHER INFORMATION CONTACT: *Regarding the draft guidance:* Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD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In September 2016, the IMDRF Management Committee endorsed the draft guidance entitled ''Software as a Medical Device (SaMD): Clinical Evaluation'' and agreed that the guidance should be made available for public comment.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

Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Antimicrobial Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Antimicrobial Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 13 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a 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/Anti-InfectiveDrugsAdvisoryCommittee/ucm094132.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. 2016–24810 Filed 10–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, codified at 5 U.S.C. App.), notice is hereby given that a meeting is scheduled for the Advisory Committee on Heritable Disorders in Newborns and Children. This meeting will be open to the public but advance registration is required to ensure sufficient webinar capacity. The registration link is *https://www.blsmeetings.net/achdncnovember2016/.* The registration deadline is Wednesday, November 2, 2016, 11:59 p.m. Eastern Time.

DATES AND TIMES: November 3, 2016, 9:00 a.m. to 5:00 p.m. (Meeting time is tentative.)

November 4, 2016, 9:00 a.m. to 1:00 p.m. (Meeting time is tentative.)

ADDRESSES: This meeting will be held by webinar only.

FOR FURTHER INFORMATION CONTACT: Anyone interested in obtaining other relevant information should contact Alaina Harris, Maternal and Child Health Bureau, HRSA, Room 18W66, 5600 Fishers Lane, Rockville, Maryland 20857; email: *aharris@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by the Public Health Service Act, Title XI, § 1111 (42 U.S.C. 300b–10), was established to advise the Secretary of the Department of Health and Human Services about 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. In addition, the Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel and constitute part of the comprehensive guidelines supported by HRSA. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13, non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (*i.e.,* policy years) beginning on or after the date that is 1-year from the Secretary's adoption of the condition for screening.

The Committee will hear presentations and discussions on topics related to 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 Committee will also hear updates from the Laboratory Standards and Procedures workgroup, Follow-up and Treatment workgroup, and Education and Training workgroup. Agenda items are subject to changes as priorities indicate. Tentatively, the Committee is expected to review and/or vote on the following: Approving newborn screening surveillance case definitions and whether or not the nominated condition Guanidinoacetate Methyltransferase deficiency should be referred for a full evidence-based review. The Committee will not be voting on a proposed addition of a condition to the Recommended Uniform Screening Panel. The meeting agenda will be available 2 days prior to the meeting on the Committee's Web site: *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

Members of the public may submit written and/or present oral comments at the meeting. All comments are part of the official Committee record. Advance registration is required to submit written comments and/or present oral comments. Written comments must be submitted by October 19, 2016, 11:59 p.m. Eastern Time in order to be included in the November meeting briefing book. Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (*i.e.,* parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments.

Individuals who wish to provide oral comments must register by October 30, 2016, 11:59 p.m. Eastern Time. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may