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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet.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 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.

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.

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 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.)

FURTHER INFORMATION CONTACT: http://www.hrsa.gov/advisorycommittees/mchb/heritableconditions/

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 copayment, 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/mchb/heritableconditions/

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