Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 601.12 and Form FDA 356h have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 607.26 and Form FDA 2830 have been approved under OMB control number 0910–0052; the collections of information in 21 CFR 606.121, 606.170, and 610.40 have been approved under OMB control number 0910–0116; and the collections of information in 21 CFR 600.14 have been approved under OMB control number 0910–0458.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27521 Filed 11–20–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0502]

Report on the Standardization of Risk Evaluation and Mitigation Strategies; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled ''Report on the Standardization of Risk Evaluation and Mitigation Strategies'' that appeared in the **Federal Register** of September 23, 2014. The document misstated the name of an organization. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Richard Currey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6125, Silver Spring, MD 20993–0002, 301–796–3918, FAX: 301–595–7910, *REMS_Standardization@fda.hhs.gov;* or Adam Kroetsch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993–0002; 301–796–3842, FAX: 301–847–8443, *REMS_Standardization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 23, 2014 (79 FR 56816), in FR Doc. 2014–22513, the following correction is made:

1. On page 56817, in the third column, under ''Draft Report Describing Findings Concerning REMS Standardization and Plans for Projects to Standardize REMS,'' ''Accreditation Commission for Education in Nursing'' is corrected to read ''American Nurses Credentialing Center.''

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27522 Filed 11–20–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Developing and Using Precision Therapies in the ''Omics'' Era: Generating and Interpreting Evidence for Rare Subsets; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public workshop entitled ''Developing and Using Precision Therapies in the 'Omics' Era: Generating and Interpreting Evidence for Rare Subsets.'' This public workshop is being cosponsored with the Center for Translational and Regulatory Sciences at the University of Virginia (UVA). The goals of this public workshop are to facilitate discussion on current scientific approaches using rare subsets during drug development programs and to further seek input from multiple stakeholders on approaches to obtain evidence that inform the regulatory evaluation of therapeutic products in rare subsets of patients identified through in-vitro diagnostic testing when specific, controlled trials are not feasible.

DATES: The public workshop will be held on December 12, 2014, from 9 a.m. to 5 p.m. Individuals who wish to attend the public workshop in person or via a live Webcast must register online by December 1, 2014, at: *https://www.signup4.net/Public/ap.aspx?OID=130&EID=DEVE96E.* Section II of this document provides attendance and registration information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. 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 *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Padmaja Mummaneni, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2164, Silver Spring, MD 20993–0002, 301–796–2027, email: *padmaja.mummaneni@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Therapeutic products are increasingly targeted to patients who have molecular characteristics that are diagnostic of a particular subtype of disease, prognostic for better or worse outcomes, or predictive of treatment response. The advent of next-generation sequencing and other high throughput technologies has enabled the development of in-vitro diagnostic tests that are able to detect rare molecular variations, specifically in the patient, tumor, or microbial DNA sequence. FDA and UVA are cosponsoring an open public workshop among stakeholders in the pharmaceutical industry, representatives from academia, regulatory scientists, and other interested parties on the development and usage of diagnostic and therapeutic products that respectively have the potential to identify and treat patients with rare molecular characteristics. It is important for regulatory agencies, pharmaceutical and diagnostic industries, and the medical community, including payers, to have a mutual

understanding of various forms of evidence that could inform regulatory and medical decision making. The public workshop will help identify key components of such an evidence framework when therapeutic effectiveness is being evaluated in patients with molecular characteristics that are rare or have not been studied in clinical trials.

II. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Individuals who wish to attend the public workshop must register on or before December 1, 2014, by visiting: *https://www.signup4.net/Public/ap.aspx?OID=130&EID=DEVE96E.*

Early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. On-site registration on the day of the public workshop will be based on space availability.

FDA will provide additional background information at the time the **Federal Register** notice is published and an agenda approximately 2 weeks before the public workshop at the FDA Meeting Information page, which is available online at: *http://wcms.fda.gov/FDAgov/Drugs/NewsEvents/ucm416622.htm?SSContributor=true.*

If you need special accommodations because of disability, please contact Padmaja Mummaneni (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the public workshop.

A live Webcast of this public workshop will be viewable on Adobe Connect at *https://collaboration.fda.gov/rsw2014/* on the day of the public workshop.

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27523 Filed 11–20–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 22, 2015, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Jennifer Shepherd, 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, FAX: 301–847–8533, email: *AIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug applications (NDAs) 207–500 and 207–501, isavuconazonium sulfate capsules and isavuconazonium sulfate for injection, sponsored by Astellas Pharma Global Development, Inc., respectively for the proposed indications of treatment of invasive aspergillosis and mucormycosis.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 7, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 29, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 30, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jennifer Shepherd at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 17, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–27573 Filed 11–20–14; 8:45 am]

BILLING CODE 4164–01–P