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