Since the claims are based on authoritative statements of a scientific body of the U.S. Government or NAS, we believe that the information that is required by the FD&C Act to be submitted with a notification will be readily available to a respondent. However, the respondent will have to collect and assemble that information. Based on communications with firms that have submitted notifications, we estimate that one respondent will take 250 hours to collect and assemble the information required by the statute for a nutrient content claim notification. Further, we estimate that one respondent will take 450 hours to collect and assemble the information required by the statute for a health claim notification.

Under the guidance, notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. The guidance applies to both nutrient content claim and health claim notifications. We have determined that this information should be readily available to a respondent and, thus, we estimate that it will take a respondent 1 hour to incorporate the information into each notification. We expect there will be two respondents for a total of 2 hours.

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27517 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 1999–D–3528 (Formerly Docket No. 1999D–5046)]

Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Guidance for Industry'' dated December 2014. The guidance document provides manufacturers of licensed whole blood and blood components intended for transfusion or for further manufacture, including source plasma, with recommendations concerning submission of changes to an approved biologics license application (BLA). The guidance document also provides manufacturers of licensed whole blood and blood components recommendations in connection with the applicability and content of comparability protocols and labeling changes. The guidance applies to the manufacture and distribution of licensed products. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2013 and supersedes the document of the same title dated July 2001 (July 2001 guidance).

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Guidance for Industry'' dated December 2014. The guidance document provides manufacturers of licensed whole blood and blood components intended for transfusion or for further manufacture, including source plasma, with recommendations concerning submission of changes to an approved BLA in accordance with the requirements under Title 21 of the Code of Federal Regulations 601.12 (21 CFR 601.12). The guidance document also provides manufacturers of licensed whole blood and blood components with recommendations in connection with the applicability and content of comparability protocols under § 601.12(e) and labeling changes under § 601.12(f). Frequently, a manufacturer of a licensed product determines that it is appropriate to make a change in its product, production process, quality controls, equipment, facilities, responsible personnel, or labeling as documented in its approved BLA(s). Section 601.12 states the requirements to report such changes for licensed biological products to FDA.

The recommendations contained in the guidance document reflect current FDA and industry experience with reporting changes to an approved application, including reporting the implementation of new technologies. The recommendations have been revised for reporting categories for certain changes to an approved application that were in the July 2001 guidance based on the experience gained over the last decade.

In the **Federal Register** of May 31, 2013 (78 FR 32668), FDA announced the availability of the draft guidance of the same title dated June 2013. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In response to comments, the guidance includes the addition of numerous appendices with tables to highlight the appropriate reporting categories related to certain manufacturing changes. The guidance announced in this notice finalizes the draft guidance dated June 2013.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork

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