preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of October 20, 2011 (76 FR 65199), FDA published a notice announcing the availability of a draft guidance entitled ''E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs): Implementation Guide—Data Elements and Message Specification'' and an appendix to the guidance entitled ''ICSRs: Appendix to the Implementation Guide—Backwards and Forwards Compatibility.'' FDA also published a correction notice (November 16, 2011, 76 FR 71044) giving interested persons an opportunity to submit comments by January 18, 2012.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in November 2012.

The guidance provides guidance on the data elements, terminology, and exchange standards for the submission of ICSRs to improve the inherent quality of adverse event data and enable improved handling and analysis of ICSRs. The E2B(R3) implementation guidance provides support for the implementation of software tools for creating, editing, sending, and receiving electronic ICSR messages. The E2B(R3) implementation guidance also provides instruction for how pharmaceutical industries and regulatory authorities should use the ''International Organization for Standardization (ISO) 27953–2 (Part 2)'' ICSR messaging standard for exchanging pharmacovigilance information among ICH regions and in other countries adopting ICH guidelines. The BFC appendix describes the relationship between data elements from E2B(R2) and E2B(R3) and is intended to assist reporters and recipients in implementing systems with special focus on the recommendations for converting back and forth between E2B(R2) and E2B(R3) ICSR reports. The E2B(R3) implementation guidance and BFC appendix are being issued as a package that includes schema files and additional technical information to be used for creating compliant ICSR files.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency'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. 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.*

III. Electronic Access

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

Dated: February 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03677 Filed 2–20–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Blood Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products 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 March 18, 2014, from 8:30 a.m. to 4:30 p.m. and March 19, 2014, from 9 a.m. to 11:30 a.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 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. For those unable to attend in person, the meeting will also be Webcast. The Webcast will be available at the following link: *https://collaboration.fda.gov/bpac2014/.* On link please enter as a guest to the site.

Contact Person: Bryan Emery or Pearline Muckelvene, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–1277 or 301–827–1281, 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: On the morning of March 18, 2014, the committee will meet in open session to discuss the evaluation of the safety and effectiveness of the Immucor PreciseType™ HEA Molecular BeadChip Assay, manufactured by BioArray Solutions Limited. In the afternoon, the committee will hear update presentations on the following topics: (1) Report from the Presidential Commission for the Study of Bioethical Issues on the ethical implications of incidental findings in clinical, research, and direct-to-consumer contexts; (2) summary of the January 28–29, 2014, FDA public workshop on immune globulin-associated hemolysis; and (3) a summary of the December 4–5, 2013, HHS Advisory Committee on Blood and Tissue Safety and Availability. On the morning of March 19, 2014, the committee will meet in open session to

hear presentations on the research programs of the Laboratory Hemostasis, Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA.

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: On March 18, 2014, from 8:30 a.m. to approximately 4:30 p.m., the meeting is open to the public. 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 March 11, 2014. Oral presentations from the public on March 18, 2014, will be scheduled between approximately 1:30 p.m. and 2 p.m. On March 19, 2014, from 9 a.m. to approximately 11 a.m., the meeting is open to the public. Oral presentations from the public on March 19, 2014, will be scheduled between approximately 10:30 a.m. and 11 a.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 March 3, 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 March 4, 2014.

Closed Committee Deliberations: On March 19, 2014, from approximately 11 a.m. to 11:30 a.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the site visit report of the intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. Seating for this meeting may be limited, so the public is encouraged to watch the free Webcast if unable to attend. The Webcast will be available at 8:30 a.m. on March 18, 2014, and on March 19, 2014, at 9 a.m. at the link provided.

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 Bryan Emery 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: February 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03703 Filed 2–20–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

The Tobacco Products Scientific 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: The Tobacco Products Scientific 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 April 16, 2014, from 8:30 a.m. to 5 p.m.; on April 17, 2014, from 8:30 a.m. to 5 p.m.; and on April 18, 2014, from 8:30 a.m. to 3 p.m.

Location: Center for Tobacco Products, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373.

Contact Person: Caryn Cohen, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose option 5), email: *TPSAC@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: On April 16, 2014, the committee will consider scientific issues pertaining to dependence and addiction, including the development of addiction, measurement of dependence and addiction, and concepts concerning the assessment of addiction in the review of product submissions.

On April 17, 2014, the committee will receive information on population modeling in the assessment of tobacco product applications and discuss the ways modeling can inform decisions critical to population health.

On April 18, 2014, the committee will discuss possible approaches for evaluating information on the risks and potential benefits of a proposed modified risk tobacco product to the health of individual tobacco users and to the population as a whole.

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