4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1617]

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). The meeting will be open 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 December 2, 2014, from 8:30 a.m. to 4:30 p.m. and December 3, 2014, from 8:30 a.m. to 12:30 p.m.

Addresses: FDA is opening a docket for person interested in presenting data, information, or views, orally or in writing, on issues pending before the committee. The docket number is FDA-2014-N-1617. Please see the procedure section of the notice for further information.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. 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 Web cast. The Web cast will be available at the following links:

- December 2, 2014, Blood Products Advisory Committee Web link: https://collaboration.fda.gov/bpac1214/
- December 3, 2014, Blood Products Advisory Committee Web link: https://collaboration.fda.gov/bpacdecember3/

Contact Person: Bryan Emery or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, Bldg. 71, rm. 6132, 240-402-8054 or 240-402-8106, 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 December 2, 2014, the Committee will meet in open session to hear scientific data related to reconsideration of the current blood donor deferral policy for men who have had sex with another man (MSM) even one time since 1977. The Committee will be presented with an update on the November 13, 2014, meeting of the Advisory Committee on Blood and Tissue Safety and Availability where the MSM blood donor deferral policy will be

discussed. In the afternoon, an informational presentation will be made regarding the emergence of chikungunya virus infections in the Western Hemisphere and potential implications for blood transfusion safety. The Committee will also hear an informational presentation on the first survey of the Rapid Donor Surveillance (RapidDOS) project on Middle Eastern Respiratory Syndrome coronavirus (MERS-CoV).

On December 3, 2014, the Blood Products Advisory Committee will be seated as a device classification panel. In open session, the panel will discuss the appropriate device classification of blood establishment computer software (BECS) and accessories to BECS. Blood establishment computer software is currently subject to the premarket notification [510(k)] provisions of the Federal Food, Drug and Cosmetic Act.

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 November 25, 2014. On December 2, 2014, oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. On December 3, 2014, oral presentations from the public will be scheduled between approximately 10:30 a.m. to 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 November 18, 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 November 19, 2014.

FDA has opened a docket for the public who are interested in presenting data, information, or views, orally or in writing, on issues pending before the committee. The docket number is FDA-2014-N-1617. The docket will close November 25, 2014. Interested persons are encourages to use the docket to submit electronic or written comments regarding this meeting. Submit electronic comments to http://www.regulations.gov.

Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified 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.

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: October 16, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014-25067 Filed 10/21/2014 at 8:45 am; Publication Date: 10/22/2014]