4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Blood Products Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of the meeting of the Blood Products Advisory Committee. This meeting was announced in the Federal Register of October 22, 2014. The amendment is being made to reflect a change in the Agenda portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Bryan Emery or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 6132, Silver Spring, MD 20993, 240-402-8054 or 240-402-8129, 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.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 22, 2014 (79 FR 63131), FDA announced that a meeting of the Blood Products Advisory Committee would be

held on December 2 and 3, 2014. On page 63131, in the third column, the Agenda portion of the document is changed to read as follows:

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 U.S. Department of Health and Human Services Advisory Committee on Blood and Tissue Safety and Availability where the MSM blood donor deferral policy will be discussed. In the afternoon, the Committee will hear an informational presentation on Ebola virus, the potential implications for blood safety in the United States and FDA's considerations on the collection of convalescent plasma for investigational use.

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. 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)

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: November 10, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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