4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6358]

Blood Products Advisory Committee Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Blood Products Advisory Committee (the Committee). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues related to blood and products derived from blood. The meeting will be open to the public.

DATES: The meeting will be held on November 30, 2017, from 8 a.m. to 5:45 p.m. and on December 1, 2017, from 8 a.m. to 3:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD, 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

FOR FURTHER INFORMATION CONTACT: Bryan Emery or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002, Bldg. 71, Rm. 6132, at 240-402-8054, bryan.emery@fda.hhs.gov and 240-402-8106, joanne.lipkind@fda.hhs.gov respectively, 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 website at https://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. For those unable to attend in person, the meeting will also be available via Webcast. The Webcast will be available at the following link for both days: https://collaboration.fda.gov/bpac2017.

SUPPLEMENTARY INFORMATION:

Agenda: On November 30, 2017, the Committee members will meet in open session to discuss bacterial risk control strategies for blood collection establishments and transfusion services to enhance the safety and availability of platelets for transfusion. In the afternoon, the Committee will be seated as a device classification panel. In open session, the panel will discuss the appropriate device classification of human leukocyte antigen, human platelet antigen, and human neutrophil antigen devices. On December 1, 2017, the committee members will meet in open session to discuss strategies to reduce the risk of transfusion-transmitted Zika virus. In the afternoon, an information session on the Transfusion Transmissible Infections Monitoring System will be presented to the Committee. Finally, the Committee will hear an update presentation on the April 6, 2017, FDA public workshop on emerging tick-borne diseases and blood safety.

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 website 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 website after the meeting. Background material is available at https://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 22, 2017. Oral presentations from the public will be scheduled between approximately 11:35 a.m. to 12:20 p.m. and 4:15 p.m. to 4:45 p.m. on November 30, 2017. Oral presentations from the public will also be scheduled between approximately 10:45 a.m. and 11:30 a.m. and 3 p.m. to 3:30 p.m. on December 1, 2017. 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 14, 2017. 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 15, 2017.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due

to a disability, please contact Bryan Emery or Joanne Lipkind at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at https://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: November 6, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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