4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0573]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Blood Products Advisory Committee (BPAC). 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 committee will discuss scientific considerations for cold stored platelet products intended for transfusion. The meeting will be open to the public.

DATES: The meeting will be held on November 22, 2019, from 8:30 a.m. to 4:45 p.m.

ADDRESSES: Tommy Douglas Conference Center, 10000 New Hampshire Ave., Silver Spring, MD 20993. Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, may be accessed at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm. Information about the Tommy Douglas Conference Center may be accessed at: https://www.tommydouglascenter.com/.

For those unable to attend in person, the meeting will also be webcast; please see the following link for webcast and other meeting information: https://www.fda.gov/advisory-

committees/blood-products-advisory-committee/2019-meeting-materials-blood-products-advisory-committee.

FOR FURTHER INFORMATION CONTACT: Christina Vert or Joanne Lipkind, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6268, Silver Spring, MD 20993-0002, 240-402-8054, christina.vert@fda.hhs.gov, or 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.

SUPPLEMENTARY INFORMATION:

Agenda: On November 22, 2019, the BPAC will meet in open session to discuss scientific considerations for cold stored platelet products intended for transfusion, including product characterization, duration of storage and clinical indications for use. The committee will hear presentations on available characterization and functional studies of cold stored platelets, clinical studies, and the potential role of cold stored platelets in clinical care in military and civilian patient populations. The committee will also discuss the clinical studies needed to support the indications for use of cold stored platelet products stored beyond 3 days.

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. For those unable to attend in person, the meeting will also be webcast; please see the following link for webcast and other meeting information: https://www.fda.gov/advisory-committees/blood-products-advisory-committee/2019-meeting-materials-blood-products-advisory-committee.

Procedure: On November 22, 2019, from 8:30 a.m. to 4:45 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 November 13, 2019. Oral presentations from the public will be scheduled between approximately 2:35 p.m. and 3:35 p.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 4, 2019. 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 5, 2019.

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 Christina Vert (see FOR FURTHER INFORMATION CONTACT) 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: September 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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