4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Blood Products 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 general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on April 4, 2017, from 8:30 a.m. to 3:45 p.m. and on April 5, 2017, from 8:30 a.m. to 12 p.m.

ADDRESSES: The meeting will be held at Tommy Douglas Conference Center, 10000 New Hampshire Ave., Silver Spring, MD 20903. The conference center's telephone number is 240-645-4000. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.tommydouglascenter.com.

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 20993-0002, 240-402-8054, 240-402-8106, bryan.emery@fda.hhs.gov, joanne.lipkind@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. 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: April 4, 2017, 115th Meeting of the Blood Products Advisory Committee--Day 1 at: http://fda.yorkcast.com/webcast/Play/bb044b891a7b48ff82cc30b18ece526e1d; April 5, 2017, 115th Meeting of the Blood Products Advisory Committee--Day 2 at: http://fda.yorkcast.com/webcast/Play/b4068ead1c874966860584b421dcfd231d.

SUPPLEMENTARY INFORMATON:

Agenda: On April 4, 2017, in open session, the Committee will discuss Recombinant Human Coagulation Factor IX, GlycoPEGylated. In the afternoon, in open session, the Committee will hear an update presentation on a summary of responses to Docket FDA-2016-N-1502: Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.

On April 5, 2017, in open session, the committee will hear overview presentations on the research programs in the Laboratory of Emerging Pathogens in the Division of Emerging Transfusion-Transmitted Diseases, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA. At the conclusion of the open session, the meeting will be closed to permit discussion where disclosure would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C 552b(c)(6). During the closed session, the

Committee will discuss the research progress made by staff involved in the intramural research programs and make recommendations regarding their personnel actions and staffing decisions.

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 March 28, 2017. Oral presentations from the public will be scheduled between approximately 10:50 a.m. to 11:20 a.m. and will be scheduled between approximately 3:15 p.m. to 3:45 p.m. on April 4, 2017. Oral presentations from the public will be scheduled between approximately 10:15 a.m. and 11:15 a.m. on April 5, 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 March 20, 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 March 21, 2017.

Closed Committee Deliberations: On April 5, 2017, from 11:15 a.m. to 12:00 p.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 report of the intramural research program 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.

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 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 24, 2017.

Janice M. Soreth,

Associate Commissioner for Special Medical Programs.

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