4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

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 September 20, 2012, from 8 a.m. to 5 p.m. and September 21, 2012, from 8 a.m. to 4 p.m.

Location: 5630 Fishers Lane, rm. 1066, Rockville, MD 20857. For those unable to attend in person, the meeting will also be Web cast. The Web cast will be available at the following links: On September 20, 2012, Blood Products Advisory Committee Day 1, http://fda.yorkcast.com/webcast/Viewer/?peid=27146555dd9347f09571f29589297e0c1d and on September 21, 2012, Blood Products Advisory Committee Day 2, http://fda.yorkcast.com/webcast/Viewer/?peid=8effe88a1e834779b4932f882b67e3391d.

Contact Person: Bryan Emery or Pearline Muckelvene, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-1281, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-

443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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 September 20, 2012, the committee will discuss hepatitis E virus and blood transfusion safety. In the afternoon, the committee will discuss Octapharma's biologics license application for Pooled Plasma (Human, Solvent/Detergent Treated). On September 21, 2012, the committee will discuss considerations for strategies to further reduce the risk of bacterial contamination in Platelets. In the late afternoon the committee will hear the following update: Summary of September 6-7, 2012, public workshop on the risks and benefits of hydroxyethyl starch solutions.

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 September 13, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11:15 a.m. and 3:30 p.m. to 4 p.m. on September 20, 2012, and also between approximately 1 p.m. and 2 p.m. on September 21, 2012. 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 September 5, 2012. 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 September 6, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. The public is encouraged to watch the free Web cast if you are unable to attend this meeting. The link for the Web cast will be available at 8 a.m. each day September 20-21, 2012, located under the Location section of this notice.

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, 301-827-1277, or Pearline Muckelvine, 301-827-1281, 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: July 26, 2012.
Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

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