

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

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 July 20, 2009, from 8 a.m. to 6 p.m. and on July 21, 2009, from 9 a.m. to 12 noon.

Location: Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877, 301-977-8900.

Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike (HFM-71), Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 20, 2009, in the morning, the committee will review proposed strategies to demonstrate the effectiveness of new coral snake antivenoms. In the afternoon, the committee will discuss alternative clinical and surrogate endpoints for evaluating efficacy of Alpha-1 Proteinase Inhibitor (Human) augmentation therapy in Alpha-1 antitrypsin deficiency. Alpha-1 antitrypsin deficiency is a genetic condition associated with decreased circulating levels of alpha-1 antitrypsin that significantly increases the risk of

serious lung disease (i.e. emphysema) in adults. On July 21, 2009, the committee will hear updates on the following topics: The April 30 to May 1, 2009, meeting of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability (<http://www.hhs.gov/ophs/bloodsafety/index.html>); the June 12, 2009, meeting of the FDA Transmissible Spongiform Encephalopathies Advisory Committee (<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/TransmissibleSpongiformEncephalopathiesAdvisoryCommittee/ucm129559.htm>); and an overview of the epidemiology and virology of the 2009 A/H1N1 influenza virus and its impact on the U.S. blood system. The committee will also hear informational presentations on recent public and private hemovigilance efforts, including the pilot hemovigilance module in the National Healthcare Safety Network.

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 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 July 15, 2009. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. and between approximately 3:45 p.m. and 5 p.m. on July 20, 2009, and between approximately 11:30 a.m. and 12 noon on July 21, 2009. Those desiring to make 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 July 13, 2009. 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 July 8, 2009.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Pearline K. Muckelvene 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/ucm11462.htm> for procedures on public conduct during advisory committee meetings.

FDA regrets that it was unable to publish this notice 15 days prior to the July 20, 2009, Blood Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Blood Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 29, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

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Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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