

hydrochloride suppository product that is not the subject of an approved NDA will then be unlawful.

We note that under enforcement policies regarding drugs marketed without required applications described in the agency's guidance entitled *Marketed Unapproved Drugs—Compliance Policy Guide*, it is a high priority for the agency to take enforcement action against those unapproved drug products that lack evidence of effectiveness. Firms should be aware that we intend to take enforcement action without further notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice after May 9, 2007. Firms that discontinue or have already discontinued manufacturing products covered by this notice may want to notify us that they are no longer manufacturing those products. A firm that wishes to notify us of product discontinuation should send a letter, signed by the firm's chief executive officer, fully identifying the discontinued product, including its National Drug Code (NDC) number. The firm should send the letter to the Division of New Drugs and Labeling Compliance, New Drugs and Labeling Team (see **ADDRESSES**). Firms should also update the listing of their products under section 510(j) of the act (21 U.S.C. 360(j)) to reflect discontinuation of unapproved or otherwise discontinued products. We plan to rely on our existing records, the results of a subsequent inspection, or other available information when we evaluate whether to take enforcement action.

Dated: March 14, 2007.

**Douglas C. Throckmorton,**

*Deputy Director, Center for Drug Evaluation and Research.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**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 April 26, 2007, from 2 p.m. to 6 p.m. and on April 27, 2007, from 8 a.m. to 3:30 p.m.

*Location:* Hilton Hotel, Washington, DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

*Contact Person:* Donald W. Jehn or Pearlina 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.

*Agenda:* On April 26, 2007, the committee will hear an update on a summary of August 30 and 31, 2006, meeting of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability. The committee will then discuss issues related to implementation of blood donor screening for infection with *Trypanosoma cruzi* and issues related to transmissibility of *Trypanosoma cruzi* in donors of human cells, tissue, and cellular and tissue-based products. On April 27, 2007, the committee will hear updates on summary of December 15, 2006, meeting of the Transmissible Spongiform Encephalopathies Advisory Committee, FDA's risk communication on plasma-derived Factor VIII and Factor XI, and summary of September 25 and 26, 2006, FDA Workshop on Molecular Methods in Immunohematology. The committee will then discuss transfusion related acute lung injury, and discuss issues related to implementation of blood donor screening for infection with West Nile Virus.

FDA intends to make background material available to the public no later than 1 business day 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/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and 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 April 18, 2007. Oral presentations from the public will be scheduled between approximately 4:30 p.m. and 5 p.m. on April 26, 2007, and between approximately 10:45 a.m. and 11:15 a.m. on April 27, 2007. 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 April 10, 2007. 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 April 11, 2007.

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 Donald W. Jehn or Pearlina K. Muckelvene at least 7 days in advance of the meeting.

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

Dated: April 3, 2007.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.