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.

[FR Doc. E7–6593 Filed 4–6–07; 8:45 am]

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 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.

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 Encephelopathies 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 Pearline 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.

[FR Doc. E7–6594 Filed 4–6–07; 8:45 am]

BILLING CODE 4160–01–S

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.

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: General Hospital and Personal Use Devices Panel of the Medical Devices 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 May 4, 2007, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Scott Colburn, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville MD, 20850, 240–276–3707, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512520. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on the scientific and clinical issues raised by the addition of antimicrobial agents to personal protective equipment (PPE). The PPE to be discussed are surgical masks/respirators, medical gloves, and surgical/isolation gowns.

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 20, 2007. Oral presentations from the public will be scheduled for approximately 30 minutes during the morning deliberations and for approximately 30 minutes during the afternoon deliberations. 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 12, 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 13, 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 AnnMarie Williams, Committee Management Staff, at 301–827–7291 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.

[FR Doc. E7–6645 Filed 4–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0121]

Use of Medication Guides to Distribute Drug Risk Information to Patients; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing a public hearing to obtain feedback on FDA's Medication Guide program, which provides for the distribution of FDA-approved written patient information for certain drug and biological products that pose serious and significant public health concerns. FDA is interested in obtaining public comment on ways to improve communication to patients who receive Medication Guides. The purpose of the public hearing is to solicit information and views from interested persons on specific issues associated with the development, distribution, comprehensibility, and accessibility of Medication Guides, which are required to convey risk information to patients.

Dates and Times: The public hearing will be held on June 12 and 13, 2007, from 8:30 a.m. to 4:30 p.m. on both days. Submit written or electronic notices of participation by 4:30 p.m. on May 12, 2007. Written and electronic comments will be accepted until July 12, 2007.

Location: The public hearing will be held at the National Transportation and Safety Board Boardroom and Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594 (Metro: L'Enfant Plaza Station on the Green, Yellow, Blue, and Orange Lines).

Addresses: Submit written or electronic notices of participation to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or on the Internet at *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*. Submit written or electronic comments to *http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm* or to the Division of Dockets Management. Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.fda.gov/ohrms/dockets* approximately 21 days after the hearing.

For Registration to Attend and/or to Participate in the Meeting: Seating at the meeting is limited. People interested in attending should register at *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm* or submit a written request for registration to the Division of Dockets Management (see *Addresses*) by 4:30 p.m. on May 12, 2007. Registration is free and will be on a first-come, first-served basis.

If you wish to make an oral presentation during the open session of the meeting, you must state this intention on your notice of participation (see *Addresses*) and provide an abstract of your presentation by May 12, 2007. In the notice, submit your name, title, business affiliation, address, telephone and fax numbers, and e-mail address. FDA has identified questions and subject matter of special interest in section II of this document. You should also identify the subject matter and question number you wish to address in your presentation, and the approximate time requested for your presentation. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. FDA may require joint presentations by persons with common interests. We will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. You must submit final electronic presentations, if any, to Mary Gross (see *Contacts*) by no later than June 6, 2007.

Contacts: Mary C. Gross, Safety Policy and Communication Staff (HFD–001), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane,