both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 3, 2007.

Diane Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–6591 Filed 4–6–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Environmental Health/Agency for Toxic Substances and Disease Registry; The Board of Scientific Counselors (BSC), Centers for Disease Control and Prevention (CDC), National Center for Environmental Health (NCEH)/Agency for Toxic Substances and Disease Registry (ATSDR): Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC and ATSDR announce the following meeting of the aforementioned committee:

Times and Dates: 8 a.m.–4:45 p.m., May 17, 2007. 8 a.m.–12 p.m., May 18, 2007.

Place: 1825 Century Boulevard, Atlanta, Georgia 30345.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: The Secretary, Department of Health and Human Services (HHS), and by delegation, the Director, CDC, are authorized under Section 301 (42 U.S.C. 241) and Section 311 (42 U.S.C. 243) of the Public Health Service Act, as amended, to: (1) Conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments; (2) assist states and their political subdivisions in the prevention of infectious diseases and other preventable conditions and in the promotion of health and well being; and (3) train state and local personnel in health work. The BSC, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC, and Administrator, ATSDR; and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agency's mission to protect and promote people's health. The board provides advice and guidance that will assist NCEH/ATSDR in ensuring scientific quality, timeliness, utility, and dissemination of results. The board also provides guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America's health.

Matters To Be Discussed: An update on NCEH/ATSDR's Office of the Director; an update on Science and Public Health and Reports; an update on the Health Department Subcommittee, the Community and Tribal Subcommittee, and the Program Peer Review Subcommittee (PPRS) Reports and Discussion; a presentation on CDC's Web site redesign and the NCEH/ATSDR Web site; an update on Climate Change Initiative; a presentation on the Office of Tribal Affairs' Expert Panel Report; an update on issues from the Board; a discussion on the Office of Management and Budget Performance Assessment and Review Techniques goals and objectives; an update on the National Exposure Report; an update on Preparedness and Emergency Response priorities and portfolio; and a discussion on BSC—PPRS Draft Peer Review Report on ATSDR Site-Specific Activities.

Agenda items are tentative and subject to change.

FOR FURTHER INFORMATION CONTACT: Sandra Malcom, Committee Management Specialist, NCEH/ATSDR, 1600 Clifton Road, Mail Stop E–28, Atlanta, Georgia 30303; telephone 404/498–0003, fax 404/498–0622; E-mail: *smalcom@cdc.gov*. The deadline for notification of attendance is May 4, 2007.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and NCEH/ATSDR.

Dated: April 2, 2007.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–6585 Filed 4–6–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1978N–0224 (formerly Docket No. 78N–0224); DESI 11853]

Trimethobenzamide Hydrochloride Suppositories; Withdrawal of Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the resolution of issues concerning trimethobenzamide hydrochloride suppositories. This notice announces the withdrawal of approval of the new drug application (NDA) for Tigan (trimethobenzamide hydrochloride) Suppositories. The notice also declares that the marketing of unapproved trimethobenzamide hydrochloride suppository products is unlawful and subject to FDA regulatory action. FDA is taking these actions because trimethobenzamide hydrochloride suppositories lack substantial evidence of effectiveness.

ADDRESSES: Requests for an opinion on the applicability of this notice to a specific trimethobenzamide hydrochloride suppository product should be identified with Docket No. 1978N–0224 and reference number DESI 11853 and directed to the Office of Compliance, Division of New Drugs and Labeling Compliance (HFD–310), New Drugs and Labeling Team, Center for Drug Evaluation and Research, Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852.

DATE: Effective May 9, 2007.

FOR FURTHER INFORMATION CONTACT: Brian L. Pendleton, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

As part of its Drug Efficacy Study Implementation (DESI) program, in a notice published in the **Federal Register** on February 24, 1971 (36 FR 3435) (the 1971 notice), FDA announced the following conclusions regarding certain drug products that contain trimethobenzamide hydrochloride: (1) The products were probably effective for nausea and vomiting due to radiation therapy or travel sickness and for emesis associated with operative procedures, labyrinthitis, or Meniere's syndrome; (2) they were lacking substantial evidence

of effectiveness for the treatment of nausea and vomiting due to infections, underlying disease processes, or drug administration; and (3) they were possibly effective for all other labeled indications. The 1971 notice listed three trimethobenzamide hydrochloride products: Tigan Solution for Injection (NDA 11–853), Tigan Capsules (NDA 11–854), and Tigan Suppositories (NDA 11–855). Roche Laboratories held the NDAs for these three products.

On January 9, 1979, we published a notice in the **Federal Register** (44 FR 2021) (the 1979 suppository notice) announcing that we were reclassifying trimethobenzamide hydrochloride suppositories to lacking substantial evidence of effectiveness and proposing to withdraw approval of the NDAs for trimethobenzamide hydrochloride suppositories. The 1979 suppository notice stated that NDA 17–529 for Tigan Suppositories, held by Beecham Laboratories (Beecham), had not been included in the 1971 notice, but was affected by the new notice. (In the same issue of the January 9, 1979, **Federal Register** (44 FR 2017) (the 1979 injection and capsule notice), we published a notice announcing that we were reclassifying trimethobenzamide hydrochloride injection and capsules to effective for certain indications and to lacking substantial evidence of effectiveness for their other (previously designated) less-than-effective indications. On December 24, 2002, we published the final evaluation for trimethobenzamide hydrochloride injection and capsules (67 FR 78476).)

In the 1979 suppository notice, we gave notice of an opportunity for a hearing to the holders of the NDAs for trimethobenzamide hydrochloride suppositories, and to all other interested persons, stating that we proposed to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of the NDAs and all amendments and supplements thereto (44 FR 2021 at 2021 to 2022). We stated that the notice of an opportunity for a hearing encompassed all issues relating to the legal status of the drug products subject to the notice, including identical, related, or similar drug products as defined in § 310.6 (21 CFR 310.6) of our regulations. In accordance with section 505 of the act and parts 310 and 314 (21 CFR parts 310 and 314), we gave the holders of the NDAs and all other persons who manufacture or distribute a drug product that is identical, related, or similar to a drug product named in the notice an opportunity for a hearing to show why approval of the NDAs involved should not be withdrawn, and an opportunity to raise, for administrative determination, all issues relating to the legal status of a named drug product and all identical, related, or similar drug products (44 FR 2021 at 2022).

The 1979 suppository notice stated that the failure of an applicant or any other person subject to the notice to file a timely written appearance and request for a hearing, as required by § 314.200, constituted an election by the person not to make use of the opportunity for a hearing and a waiver of any contentions concerning the legal status of any drug product subject to the notice. The notice further stated that any such drug product could not thereafter lawfully be marketed, and we would initiate appropriate regulatory action to remove such drug products from the market (44 FR 2021 at 2022).

In a letter dated January 30, 1979, Beecham requested a hearing on the proposed withdrawal of NDA 17–529 for Tigan Suppositories. In a letter dated March 5, 1979, Beecham submitted data in support of its request for a hearing. Beecham was the only party to request a hearing. On April 13, 1979, we published a notice in the **Federal Register** announcing that we were withdrawing the approval of NDA 11–8550 (the only other NDA named in the 1979 suppository notice), effective April 23, 1979 (44 FR 22199).

On November 12, 1999, King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620 (King), purchased from Roberts Pharmaceutical Corp. the NDAs for the Tigan products previously held by Beecham: NDA 17–529 (suppositories), NDA 17–530 (injection), and NDA 17–531 (capsules). We subsequently initiated discussions with King on bringing the Tigan products into compliance with the 1979 notices on trimethobenzamide hydrochloride drugs.

In an agreement that became effective on August 16, 2001 (the Agreement), FDA and King agreed to take several actions to resolve the matter of the compliance of Tigan products with the 1979 notices. Among other things, King agreed to withdraw the request for a hearing (originally submitted by Beecham) on matters related to NDAs 17–529 (Tigan Suppositories), 17–530 (Tigan Injection), and 17–531 (Tigan Capsules), and all amendments and supplements thereto, within 10 days of the effective date of the Agreement. In a letter dated August 24, 2001, King withdrew its request for a hearing on these matters in accordance with the Agreement. The issues relating to Tigan Capsules and Injection were resolved in 2001 and 2002, and on December 24, 2002, we published a notice in the **Federal Register** announcing our final evaluation of these products (67 FR 78476).

II. Resolution of Issues Concerning Tigan Suppositories

King notified us in a letter dated March 21, 2005, that it had decided not to pursue additional studies for Tigan Suppositories. In a letter dated August 19, 2005, we asked King, in accordance with the Agreement, to request the withdrawal of NDA 17–529 for Tigan Suppositories. In a letter dated September 6, 2005, King requested that we withdraw NDA 17–529.

As stated in section I of this document, King has withdrawn its request for a hearing on matters related to NDA 17–529. No party other than Beecham (a previous holder of NDA 17–529) submitted a request for a hearing in response to the 1979 suppository notice. Therefore, all other parties waived any possible contentions regarding the legal status of their trimethobenzamide hydrochloride suppository products.

III. Withdrawal of Approval of NDA 17–529 for Tigan Suppositories

As a result of the events described in section II of this document, we have concluded that Tigan Suppositories have not been shown to be effective. Therefore, we are withdrawing approval of the NDA for this product.

Under § 310.6, this notice applies to any drug product that is identical, related, or similar to Tigan Suppositories and is not the subject of an approved NDA. Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of New Drugs and Labeling Compliance (see **ADDRESSES**).

The Director of the Center for Drug Evaluation and Research, under section 505(e) of the act and under the authority delegated to him, finds that, on the basis of the information in this docket on Tigan Suppositories (NDA 17–529), evaluated together with the evidence available to FDA when the application for this product was approved, there is a lack of substantial evidence that this product has the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

Therefore, based on the foregoing finding, the approval of NDA 17–529, including all amendments and supplements thereto, is withdrawn effective May 9, 2007. Shipment in interstate commerce of Tigan Suppositories or any identical, related, or similar trimethobenzamide

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.