Branch. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03–3873 Filed 2–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Subcommittee of the Anti-Infective Drugs 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: Pediatric Subcommittee of the Anti-Infective Drugs 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 March 3, 2003, from 8 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or e-mail: perezt@cder.fda.gov or FDA Advisory Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 3, 2003, the subcommittee will discuss the development of antiretroviral drugs in human immunodeficiency virus (HIV)-infected and HIV-exposed neonates younger than 4 weeks of age. Following this at 2:45 p.m., the agency will provide an update to the subcommittee on the Adverse Event Reporting plan as mandated in section 17 of the Best Pharmaceuticals for Children Act. After this presentation, at approximately 3:45 p.m., the agency will provide an update on pediatric initiatives within the agency.

The background material for this meeting will be posted on the Internet when available, or 1 working day before the meeting at http://www.fda.gov/ohrms/dockets/ac/menu.htm.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by February 21, 2003. Oral presentations from the public will be scheduled between approximately 9:50 a.m. and 10:50 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by February 21, 2003, 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.

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 notify Thomas Perez at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Pediatric Subcommittee of the Anti-Infective Drugs 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: February, 10, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–4001 Filed 2–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastrointestinal Drugs 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Gastrointestinal Drugs 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 March 6, 2003, from 8:30 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD, 301–948–8900.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6758, or e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12538. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 6, 2003, the committee will discuss new drug application 21–549, EMEND (aprepitant) Capsules, Merck & Co., Inc., for the following indication: ''EMEND, in combination with other antiemetic agents, is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy, including high-dose cisplatin.''

Background material for this meeting will be available 1 business day before the meeting on the Internet at http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.

Procedure: On March 6, 2003, from 8:30 a.m. to 4 p.m., the meeting is open to the public. 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 by February 26, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 26, 2003, 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.

Closed Committee Deliberations: On March 6, 2003, from 4 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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 Thomas H. Perez 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: February 11, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–4002 Filed 2–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System 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: Circulatory System 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 March 6, 2003, from 10:30 a.m. to 5:30 p.m.

Location: Gaithersburg Marriott Washingtonian Center, Salons A, B, and C, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, ext. 143, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a thermal (cold) cardiac ablation catheter and generator system intended for cryoablation of cardiac tissue to treat patients with atrioventricular tachycardia and for mapping of the atrioventricular node. Background information, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at http://www.fda.gov/cdrh/panelmtg.html. Material for the March 6, 2003, meeting will be posted on March 5, 2003.

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 by February 19, 2003. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 19, 2003, 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.

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, Conference Management Staff, 301–594–1283, ext. 113, 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: February 10, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–3999 Filed 2–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0025]

Medical Devices: Draft Guidance for Industry and FDA; The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6; Draft Guidance for Industry and FDA.'' The draft guidance document is intended to assist facilities and their personnel in meeting the MQSA final regulations. This document deals with requirements related to testing of the automatic exposure control (AEC) component of mammography units.

DATES: Submit written or electronic comments on the draft guidance by May 20, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6; Draft Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to