

considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application.

Dated: January 31, 2007.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E7-2077 Filed 2-7-07; 8:45 am]

BILLING CODE 4163-18-P

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). At least one portion of the meeting will be closed 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 1, 2007, from 8 a.m. to 5:30 p.m., and March 2, 2007, from 8 a.m. to 6 p.m.

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

Contact Person: James Swink, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4179, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 1, 2007, the committee will discuss and make recommendations regarding the premarket approval application, sponsored by Medtronic Inc., for the Chronicle Implantable Hemodynamic Monitoring System. This implantable device is intended to reduce hospitalization events or equivalent

events for worsening heart failure in patients with moderate to advanced heart failure. On March 2, 2007, the committee will discuss and make recommendations regarding clinical trial designs for Patent Foreman Ovale closure devices intended to prevent recurrent stroke.

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: On March 1, 2007, from 8 a.m. to 5:30 p.m., and March 2, 2007, from 8 a.m. to 10 a.m. and 12 p.m. to 6 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 on or before February 23, 2007. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations on each day and for approximately 30 minutes near the end of the committee deliberations on each day. 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 February 15, 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 February 16, 2007.

Closed Presentation of Data: On March 2, 2007, from 10 a.m. to 12 p.m., the meeting will be closed to permit the discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) presented by sponsors.

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, 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: February 1, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7-2122 Filed 2-7-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0091]

Guidance for Industry on User Fee Waivers for Fixed Dose Combination and Co-Packaged Human Immunodeficiency Virus Drugs for the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR." This guidance describes the circumstances under which user fees will not be assessed for certain applications for fixed dose combination (FDC) and co-packaged versions of previously approved antiretroviral therapies for the treatment of human immunodeficiency virus (HIV) under the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief (PEPFAR). The guidance also describes some circumstances under which most of the applications that will be assessed fees may be eligible for a public health or a barrier-to-innovation waiver.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-