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–

240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this guidance document.

FOR FURTHER INFORMATION CONTACT: Michael Jones, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR.'' The guidance describes the circumstances under which user fees will not be assessed for certain applications for FDC and co-packaged versions of previously approved antiretroviral therapies for the treatment of HIV under PEPFAR. The guidance also describes some circumstances under which some of the applications that will be assessed fees may be eligible for a public health or a barrier-to-innovation waiver.

In May 2004, as part of PEPFAR, FDA issued a draft guidance entitled ''Fixed Dose Combination and Co-Packaged Drug Products for the Treatment of HIV'' (Fixed Dose Guidance) (69 FR 28931, May 19, 2004). The draft Fixed Dose Guidance described some scenarios for approval of FDC or co-packaged products for the treatment of HIV and provided examples of drug combinations considered acceptable for FDC/co-packaging and examples of those not considered acceptable for FDC/co-packaging. The guidance also explained that the Federal Food, Drug, and Cosmetic Act provides for certain circumstances in which FDA can grant sponsors a waiver or reduction in fees. The guidance also stated that the agency was evaluating the circumstances under which it may grant user fee waivers or reductions for sponsors developing FDC and co-packaged versions of previously approved antiretroviral therapies for the treatment of HIV. Since issuance of the draft Fixed Dose Guidance, several potential applicants have asked that we clarify whether sponsors submitting drug applications covered by the draft Fixed Dose Guidance and proposed for use in the PEPFAR program will be required to pay user fees under the Prescription Drug User Fee Act (PDUFA) and, if so, whether they would be eligible for a waiver of those fees.

In the **Federal Register** of April 18, 2005 (70 FR 20145), FDA announced the availability of a draft version of this guidance. FDA did not receive any comments in response to that draft guidance, and the agency has made only minor editorial changes to the guidance.

This guidance describes some of the scenarios under which a sponsor could qualify for fee exemptions or would only be assessed a half fee, either because the sponsor is using an active ingredient that has already been approved or the application does not require clinical data for approval. A sponsor of an application that would be assessed either a full or a half fee may also qualify for a waiver of the application fee under several provisions of PDUFA.

We expect that most of the applications, products, and establishments for FDC and co-packaged HIV therapies proposed for use in the PEPFAR program will either not be assessed fees in the first instance or will qualify for a waiver under the ''other circumstances'' part of the barrier-to-innovation user fee waiver.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on waivers for FDC and co-packaged HIV PEPFAR products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 1, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2124 Filed 2–7–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that the following committee will convene its fifty-fifth meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times: February 28, 2007, 9 a.m.–4:15 p.m., March 1, 2007, 9 a.m.–4:15 p.m., March 2, 2007, 9 a.m.–10:30 a.m.

Place: The Sofitel Lafayette Square, 806 15th Street NW., Washington, DC 20005, *Phone:* 202–730–8800.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development and administration of health and human services in rural areas.

Agenda: Wednesday morning, February 28, at 9 a.m., the meeting will be called to order by the Chairperson of the Committee, the Honorable David Beasley. Elizabeth M. Duke, Administrator of the Health Resources and Services Administration, has been invited to give opening remarks. The first presentation is titled Rural America: Then, Now and in the Future. The speakers will be John Cromartie and Carol Jones, Economic Research Service, U.S. Department of Agriculture. Following this session will be three panels on rural health and human services issues. The first will be a rural health panel with Becky Slifkin of the North Carolina Rural Health Research and Policy Analysis Center at the University of North Carolina at Chapel Hill; Gary Hart of the WWAMI Rural Health Research Center at the University of Washington; and Andy Coburn of the Maine Rural Health Research Center at the University of Southern Maine. The second will be a rural health panel with the following speakers: Julie Schoenman of the National Opinion Research Center at the University of Chicago; Michelle Casey of the