line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On February 5, 2008, the committee will meet in open session to hear updates of research programs in the Division of Therapeutic Proteins and the Division of Monoclonal Antibodies, Office of Biotechnology Products, Center for Drug Evaluation and Research, FDA.

FDA intends to make background material available to the public no later than 2 business days 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 will be available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: On February 5, 2008, from 12 noon to approximately 2:30 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 January 29, 2008. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. 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 January 21, 2008. 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 person regarding their request to speak by January 22, 2008.

Closed Committee Deliberations: On February 5, 2008, from approximately 2:30 p.m. to 3:15p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of intramural research programs and issues related to personnel progress and promotion.

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 Gail Dapolito at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 18, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–25124 Filed 12–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0481]

Draft Prescription Drug User Fee Act IV Information Technology Plan; Availability for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of the draft information technology (IT) plan entitled ''Prescription Drug User Fee Act (PDUFA) IV Information Technology Plan.'' This plan is intended to provide regulated industry and other stakeholders with information on FDA's vision and plan for improving the automation of business processes and maintaining information systems that support the process for the review of human drug applications to achieve the objectives defined in the PDUFA Performance Goals.

DATES: Submit written or electronic comments on the draft IT plan by February 22, 2008.

ADDRESSES: Submit written requests for single copies of the draft plan to the Office of the Chief Information Officer (HFA–080), 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 draft IT plan to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

FOR FURTHER INFORMATION CONTACT: Suzanne Mitri, Office of the Chief Information Officer, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–255–6700.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing for public comment the availability of the draft IT plan entitled ''Prescription Drug User Fee Act (PDUFA) IV Information Technology Plan.'' This plan is intended to provide regulated industry and other stakeholders with information on FDA's vision and plan for improving the automation of business processes and maintaining information systems that support the process for the review of human drug applications to achieve the objectives defined in section XIV, Information Technology Goals, of the PDUFA Performance Goals (*http://www.fda.gov/oc/pdufa4/pdufa4goals.html*).

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007, which includes the reauthorization and expansion of PDUFA. The reauthorization of PDUFA will significantly broaden and upgrade the agency's drug safety program, increase resources for review of television drug advertising, and facilitate more efficient development of safe and effective new medications for the American public. The reauthorization also includes Information Technology Goals that are divided into four subsections: Objectives, Communications and Technical Interactions, Standards and IT Plan, and Metrics and Measures. In addition, there are information technology goals associated with the upgrade of the agency's drug safety program in section VIII, Enhancement and Modernization of the FDA Drug Safety System.

The objectives of the PDUFA IV IT Goals are to move FDA towards the long-term goal of an automated standards-based information technology environment for the exchange, review,

and management of information supporting the process for the review of human drug applications throughout the product life cycle. As part of this process, FDA will develop and periodically update a 5-year IT plan and will solicit and consider comments from the public on the draft IT plan. At the end of the comment period, FDA will review the comments, update the IT plan, and publish the final version no later than May 30, 2008.

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 paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

III. Electronic Access

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

Dated: December 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–25310 Filed 12–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the NIH Advisory Board for Clinical Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended to discuss personnel matters, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIH Advisory Board for Clinical Research

Date: January 28, 2008.

Open: 10 a.m. to 1:15 p.m.

Agenda: To review the 2008 Clinical Center Operating Plan and provide updates on selected organizational initiatives.

Place: National Institutes of Health, Building 10, 10 Center Drive, CRC Medical Board Room 4–2551, Bethesda, MD 20892.

Closed: 1:15 p.m. to 2 p.m.

Agenda: To review and evaluate personnel matters.

Place: National Institutes of Health, Building 10, 10 Center Drive, CRC Medical Board Room 4–2551, Bethesda, MD 20892.

Contact Person: Maureen E Gormley, Executive Secretary, Mark O. Hatfield Clinical Research Center, National Institutes of Health, Building 10, Room 6–2551, Bethesda, MD 20892, 301–496–2897.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: December 18, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–6208 Filed 12–27–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the President's Cancer Panel.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will be closed to the public in accordance with the provisions set forth in section 552(c)(9)(B), Title 5 U.S.C., as amended, because the premature disclosure of information and the discussions would likely to significantly frustrate implementation of recommendations.

Name of Committee: President's Cancer Panel.

Date: January 28, 2008.

Open: January 28, 2008, 7:30 a.m.–3:30 p.m.

Agenda: Strategies for Maximizing the Nation's Investment in Cancer.

Place: Chateau Sonesta Hotel, 800 Iberville St., New Orleans, LA 70112.

Closed: January 28, 2008, 4 p.m.–6 p.m.

Agenda: Strategies for Maximizing the Nation's Investment in Cancer and discuss potential topics for the 2008/2009 series.

Place: Chateau Sonesta Hotel, 800 Iberville St., New Orleans, LA 70112.

Contact Person: Abby Sandler, PhD, Executive Secretary, National Cancer Institute, National Institutes of Health, Building 6116, Room 212, 6116 Executive Boulevard, Bethesda, MD 20892, 301–451–9399.

Any interested person may file written comments with the committee by forwarding the comments to the Contact Person listed on this notice. The comments should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person. Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/pcp/pcp.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 19, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–6186 Filed 12–27–07; 8:45 am]

BILLING CODE 4140–01–M