indicators) to evaluate care provided to CMS' beneficiaries except for demonstration projects residing in other components.

• Assures that the Agency's quality-related activities (survey and certification, technical assistance, beneficiary information, payment policies and provider/plan incentives) are fully and effectively integrated in the Field. Carries out the Health Care Quality Improvement Program for the Medicare, Medicaid, and CLIA programs.

• Assists in the specification and operational refinement of an integrated CMS quality information system, which includes tools for measuring the coordination of care between health care settings; analyzes data supplied by that system to identify opportunities to improve care and assess success of improvement interventions.

• Enforces the requirements of participation for providers and plans in the Medicare, Medicaid, and CLIA programs. Recommends revisions of the requirements based on statutory change and input from other components.

• Operates the Medicare Quality Improvement Organization and End Stage Renal Disease Network program, providing policies and procedures, contract design, program coordination, and leadership in selected projects.

• Identifies, prioritizes and develops content for clinical and health related aspects of CMS' Consumer Information Strategy; and collaborates with other components to develop comparative provider and plan performance information for consumer choices.

• Assists in the preparation of the scientific, clinical and procedural basis for, and recommends to the Administrator decisions regarding, coverage of new and established technologies and services. Maintains liaison with other Departmental components regarding the safety and effectiveness of technologies and services; prepares the scientific and clinical basis for, and recommends approaches to, quality-related medical review activities of contractors and payment policies.

• Serves as the focal point for all CMS Field activities relating to CLIA and the survey and certification of health facilities with States and Local governments (including the Territories).

• Implements, evaluates and refines standardized provider performance measures used within provider certification programs. Supports States in their use of standardized measures for provider feedback and quality improvement activities. Implements and supports the data collection and analysis systems needed by States to administer the certification program.

• Serves as the Consortium focal point for emergency preparedness for the Field.

• Provides oversight in the areas of human resource procurement and logistics.

• Ensures the effective management of the Agency's information technology and information systems and resources in the Field.

• Implements the privacy and confidentiality policies pertaining to the collection, use, and release of individually identifiable data.

• Proactively establishes, manages, and fosters partnerships within the Consortium with State and Local governments, providers and provider associations, beneficiaries and their representatives, and the media that are focused on CMS' goals and objectives.

• Serves as the primary point of contact to appropriate members of Congress, State Governors, Federal, State, and Local officials and Tribal governments on matters concerning the Medicare and Medicaid programs.

• Oversees the coordination and integration of CMS' activities with other Federal, State, Local, and private health care agencies and organizations.

• Counsels, advises, and collaborates with top Agency officials on policy matters and major considerations in developing, implementing, and coordinating CMS' programs as they interrelate in addressing national and regional strategies.

• Advises OA on special problems as they relate to national initiatives and programs and as they impact major constituents or their key representatives.

• Promotes accountability, communication, coordination and facilitation of cooperative corporate decision-making among CMS top senior staff on management, operational and programmatic issues cross-cutting organizational components with diverse functions and activities.

Dated: November 23, 2007.

Charlene Frizzera,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

[FR Doc. E7–25305 Filed 12–27–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cellular, Tissue and Gene Therapies 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: Cellular, Tissue and Gene Therapies 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 by teleconference on February 5, 2008, from 12 noon to approximately 3:15 p.m. Eastern Time.

Location: National Institutes of Health, Building 29B, Conference Room C, 9000 Rockville Pike, Bethesda, MD. This meeting will be held by teleconference. The public is welcome to attend the meeting at the specified location. A speakerphone will be provided at the specified location for public participation in the meeting, on site. Important information about transportation and directions to the NIH campus, parking, and security procedures is available on the Internet at *http://www.nih.gov/about/visitor/index.htm*. Visitors must show two forms of identification, one of which must be a government-issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. If you are planning to drive to and park on the NIH campus, you must enter at the South Dr. entrance of the campus which is located on Wisconsin Ave. (the Medical Center Metro entrance), and allow extra time for vehicle inspection. Detailed information about security procedures is located at *http://www.nih.gov/about/visitorsecurity.htm*. Because of the limited available parking, visitors are encouraged to use public transportation.

Contact Person: Gail Dapolito or Danielle Cubbage, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, 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 3014512389. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot

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,