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: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

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 17, 2010, from 7:30 a.m. to 3 p.m.

Location: Atlanta Marriott Marquis, 265 Peachtree Center Ave., Atlanta, GA 30303. The hotel phone number is 404–521–0000.

Addresses: Submit electronic comments on this document to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. Comments received on or before March 8, 2010, will be provided to the committee before the meeting. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5630 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: yvette.waples@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512539. 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 March 17, 2010, the committee will discuss and provide comments on the following topics: (1) General scientific issues related to the application of pharmacogenomics in the early stages of drug development. Pharmacogenomics examines the genetic differences that influence a person’s responses, both beneficial and harmful, to certain drugs; (2) a new patient-centric clinical pharmacology approach to drug safety; (3) the design and analysis of clinical pharmacology studies focusing on how the renal function changes in the way the body absorbs, distributes, metabolizes, and excretes a drug in patients with kidney impairment; and (4) scientific considerations and recent developments in transporter-mediated drug interactions. These interactions are between two or more drugs that either inhibit or enhance the roles of specialized proteins known as “transporters” and, in turn, the interactions can affect a drug’s safety and/or efficacy.

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 is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee link.

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 on or before March 8, 2010. Oral presentations from the public will be scheduled between approximately 9:25 a.m. and 10 a.m., and 1:15 p.m. and 1:45 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 presenters, and an outline of the topics to be discussed.

Estimated number of respondents | Estimated number of responses per respondent | Average burden hours per response | Estimated total annual burden hours requested
---|---|---|---
4,860 | 1 | 0.33 | 1,620
participants, and an indication of the approximate time requested to make their presentation on or before March 1, 2010. 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 March 2, 2010.

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 Yvette Waples 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/AdvisoryCommittees/ucm111462.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).


Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

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BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Recombinant DNA Advisory Committee.

The meeting will be open to the public, 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.

Name of Committee: Recombinant DNA Advisory Committee.

Date: March 10–11, 2010.

Time: March 10, 2010, 8 a.m. to 5:30 p.m.

Agenda: The Recombinant DNA Advisory Committee will review and discuss selected human gene transfer protocols as well as related data management activities. Additionally there will be a discussion of a proposal to exempt the mating of certain biosafety level 1 transgenic rodents from the requirements of Section III–E–3 of the NIH Guidelines for Research with Recombinant DNA Molecules. Please check the meeting agenda at http://oba.od.nih.gov/rdna/rac/rac_meetings.html for more information.


Time: March 11, 2010, 8 a.m. to 1:30 p.m.

Agenda: The Recombinant DNA Advisory Committee will review and discuss selected human gene transfer protocols as well as related data management activities. There will also be a discussion of the University of Wisconsin’s application requesting a determination of the appropriate biocontainment for the cloning of Ebola and Marburg cDNAs into E. coli. Please check the meeting agenda at http://oba.od.nih.gov/rdna/rac/rac_meetings.html for more information.


Contact Person: Laurie Lewallen, Advisory Committee Coordinator, Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892–7985, 301–496–9838, lewallen@od.nih.gov.

Information is also available on the Institute’s/Center’s home page: http://oba.od.nih.gov/rdna/rdna.html, where an agenda and any additional information for the meeting will be posted when available. OMB’s “Mandatory Information Requirements for Federal Assistance Program Announcements” (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: February 17, 2010.

Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–3585 Filed 2–23–10; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts in Memory, Cognition and Motor Control.

Date: March 2, 2010.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dana Jeffrey Plude, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–2309, pludejd@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Bone, Muscle and Cartilage Biology.

Date: March 8–9, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rajiv Kumar, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7802, Bethesda, MD 20892, 301–435–1212, kumarra@csr.nih.gov.