

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (formerly called Advisory Committee for Pharmaceutical Science); 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). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (formerly called Advisory Committee for Pharmaceutical Science).

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 May 1 and 2, 2007, from 8:30 a.m. to 5 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Victoria Ferretti-Aceto, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: Victoria.FerrettiAceto@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.

Agenda: On May 1, 2007, the committee will do the following: (1) Receive and discuss updates from the October 18 and 19, 2006, Clinical Pharmacology Subcommittee Meeting and the April 30, 2007, Manufacturing Subcommittee Meeting; (2) receive an update, discuss and make comments on current strategies and directions for the Critical Path Initiative; (3) receive an update and discuss revisions to the FDA draft guidance for industry entitled "Comparability Protocols — Chemistry, Manufacturing, and Controls Information;" (4) discuss current thinking on risk-based approaches to managing post-approval activity. On

May 2, 2007, the committee will do the following: (1) Receive an update from the Office of Generic Drugs (OGD) on the bioequivalence of highly variable drugs, (2) receive an update on and discuss general strategies within the OGD pertaining to the bioequivalence of narrow therapeutic index drug products, and (3) discuss and provide comments on the topic of alcohol-induced dose dumping.

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: 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 April 17, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 April 9, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonable 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 April 10, 2007.

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 Victoria Ferretti-Aceto 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: March 8, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7-4797 Filed 3-15-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed 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 following meeting.

The meeting 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: National Center for Research Resources Special Emphasis Panel, TSPC-SEP Teleconference.

Date: March 27, 2007.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: John R. Glowa, PhD, Scientific Review Administrator, National Center for Research Resources, or National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1078—Msc 4874, Bethesda, MD 20892-4874, 301-435-0807, glowaj@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure; 93.306, 93.333, National Institutes of Health, HHS)

Dated: March 8, 2007.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-1225 Filed 3-15-07; 8:45 am]

BILLING CODE 4140-01-M