

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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**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

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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strategies and directions for the Critical Path Initiative; (3) receive an update and discuss revisions to the FDA draft guidance for industry entitled "Comparability Protocols — Chemistry, Manufacturing, and Controls Information;" (4) discuss current thinking on risk-based approaches to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.

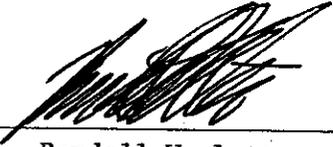
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 17, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 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: 3/8/07
March 8, 2007.



Randall W. Lutter,
Associate Commissioner for Policy and Planning.

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