

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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.

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 12, 2003, from 8:30 a.m. to 5 p.m. and March 13, 2003, from 8:30 a.m. to 5 p.m.

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

Contact Person: Kathleen Reedy or Carolyn Jones, 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, or e-mail: REEDYK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 12, 2003, the committee will: (1) Receive a final report from the Process Analytical Technology Subcommittee and provide direction

to the Manufacturing Subcommittee; (2) receive an update on sterile products produced by aseptic processing; (3) discuss and provide direction for future subcommittees: Biopharmaceutics Subcommittee and Microbiology Subcommittee; (4) discuss and provide comments on topical dermatological drug product nomenclature; and (5) discuss and provide comments on topical dermatological bioequivalence, methods development. On March 13, 2003, the committee will: (1) Discuss and provide direction for future subcommittee: Pharmacology/Toxicology Subcommittee; (2) receive an update on the Office of Pharmaceutical Science research projects; (3) discuss and provide comments on dose content uniformity, parametric interval test for aerosol products; (4) discuss and provide comments on levothyroxine bioequivalence; and (5) discuss and provide comments on comparability protocols.

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 by March 3, 2003. Oral presentations from the public will be scheduled between approximately 1:30 p.m. to 2 p.m. on March 12, 2003, and 11:30 a.m. to 12 noon on March 13, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 3, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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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 Carolyn Jones 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: January 27, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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