

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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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 April 13 and 14, 2004, 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: Hilda Scharen or Kimberly Topper, 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, e-mail: SCHARENH@cder.fda.gov or TOPPERK@cder.fda.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 April 13, 2004, the committee will receive an update from the Clinical Pharmacology Subcommittee. The committee will also discuss and

provide comments on the following topics: (1) A proposal for resolving the issues related to the parametric tolerance interval test for dose content uniformity for inhalation products, (2) the Process Analytical Technologies progress and next steps, and (3) process analytical technology for products in the Office of Biotechnology Products, Center for Drug Evaluation and Research and in the Center for Biologics Evaluation and Research. On April 14, 2004, the committee will discuss and provide comments on the following topics: (1) Bioequivalence testing/methods strategy for products exhibiting high variability and (2) bioinequivalence concepts and definition.

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 April 6, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on April 13, 2004, and 1 p.m. and 2 p.m. on April 14, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 6, 2004, 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.

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 Hilda Scharen or Kimberly Topper 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: 3/17/04
March 17, 2004.



Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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