

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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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 July 19, 2001, from 8:30 a.m. to 5:30 p.m. and July 20, 2001, from 8:30 a.m. to 3 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact: Nancy Chamberlin, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1076), Rockville, MD 20857, 301-827-7001, or e-mail: CHAMBERLINN@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 July 19, 2001, the committee will: (1) Discuss specific recommendations of the Orally Inhaled and Nasal Drug Products Subcommittee regarding dose response of locally acting nasal sprays and nasal aerosols, with particular application to bioequivalence studies; (2) hear reports and provide direction to the Nonclinical Studies Subcommittee; (3) provide comments and advice to the Risk-Based Chemistry, Manufacturing, and Controls Review Working Group for

establishment of a list of low risk drugs; (4) discuss and provide direction on optimal applications of inline process controls in pharmaceutical production; and (5) discuss problems and provide comments to form a scientific basis for establishment of acceptance limits for microbiological tests that use newly developed technologies that do not rely on colony counts, and their application as process controls and product release criteria. On July 20, 2001, the committee will: (1) Provide comments and advice on methods to determine drug transfer into breast milk and interpretation of data; and (2) discuss and provide comments on the feasibility, scientific challenges, and approaches for establishment of pharmaceutical equivalence, bioavailability, and bioequivalence of liposome drug products.

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 July 12, 2001. Oral presentations from the public will be scheduled between approximately 1:15 p.m. to 2:15 p.m. on July 19, 2001, and between approximately 10:15 a.m. to 11:15 a.m. on July 20, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 12, 2001, 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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 6/6/01
June 6, 2001.

Linda A. Suydam
Linda A. Suydam,
Senior Associate Commissioner.

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