

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 November 28 and 29, 2001, from 8:30 a.m. to 5:30 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, 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Agenda: On November 28, 2001, the committee will: (1) Discuss the current status of, and future plans for, the FDA draft guidance entitled "ANDAs: Blend Uniformity Analysis;" (2) discuss and provide direction for the Process Analytical Technology Subcommittee; (3) discuss and provide comments on stability testing and shelf life; and (4) receive updates from subcommittees and on other Center for Drug Evaluation and Research guidance documents. On November 29, 2001, the

committee will: (1) Receive updates on FDA research in dermatopharmacokinetics, and (2) discuss and provide comments on bioequivalence issues.

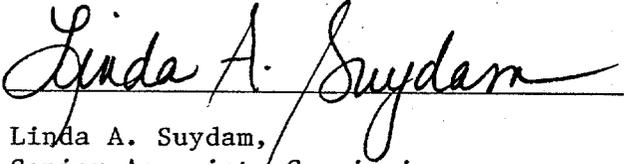
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 15, 2001. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. on November 28, 2001, and between approximately 11 a.m. and 12 noon on November 29, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 15, 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: 10/12/01

October 12, 2001.



Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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