

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 15 and 16, 2000, from 8:30 a.m. to 5:30 p.m.

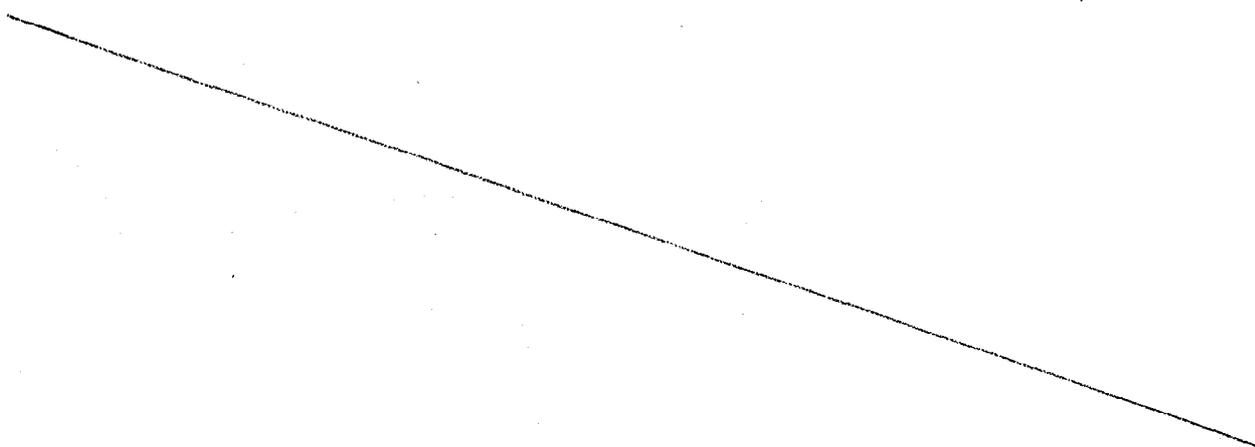
Location: University of Maryland, Shady Grove Campus, Auditorium, 9640 Gudelsky Dr., Rockville, MD 20850.

Contact Person: Nancy Chamberlin, 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: 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 15, 2000, the committee will: (1) Discuss approaches to reducing the regulatory burden for chemistry, manufacturing, and controls supplements; and (2) hear reports and provide direction to the Advisory Committee for Pharmaceutical Science's Subcommittee on Orally Inhaled and Nasal Drug Products, and to the Subcommittee on Nonclinical Studies. On November 16, 2000, the committee will: (1) Discuss the FDA guidance entitled "A Guidance

for Industry, Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System,” see the FDA Internet web address www.fda.gov/cder/guidance/3618fnl.htm under the heading of “Biopharmaceutic Guidances;” the FDA draft guidance entitled “A Guidance for Industry, BA and BE Studies for Orally Administered Drug Products-General Considerations,” see the FDA Internet web address www.fda.gov/cder/guidance/2762dft.htm under the heading of “Biopharmaceutic Draft Guidances;” and the FDA draft guidance entitled “A Guidance for Industry, Average, Population, and Individual Approaches to Establishing Bioequivalence,” see the FDA Internet web address www.fda.gov/cder/guidance/1716dft.htm under the heading of “Biopharmaceutic Draft Guidances;” (2) provide comments and advice to the Clinical Pharmacology Modeling and Simulation Working Group; (3) receive updates on both FDA intramural research and the Product Quality Research Institute; and (4) provide advice on scientific issues specific to generic drugs.

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 6, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 2000, 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: 5 Oct 00
October 5, 2000

B A Schwetz for LAS
Bernard A. Schwetz,
Acting Deputy Commissioner.

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

J. W. Dunder

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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