

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NMB

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Food and Drug Administration

Joint Meeting of the Advisory Committee for Pharmaceutical Science and the Dermatologic and Ophthalmic Drugs Advisory Committee; 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 and the Dermatologic and Ophthalmic Drugs Advisory Committee.

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 17, 2000, from 8:30 a.m. to 12:30 p.m.

Location: Quality Suites, Potomac Ballroom, 3 Research Ct., Rockville, MD.

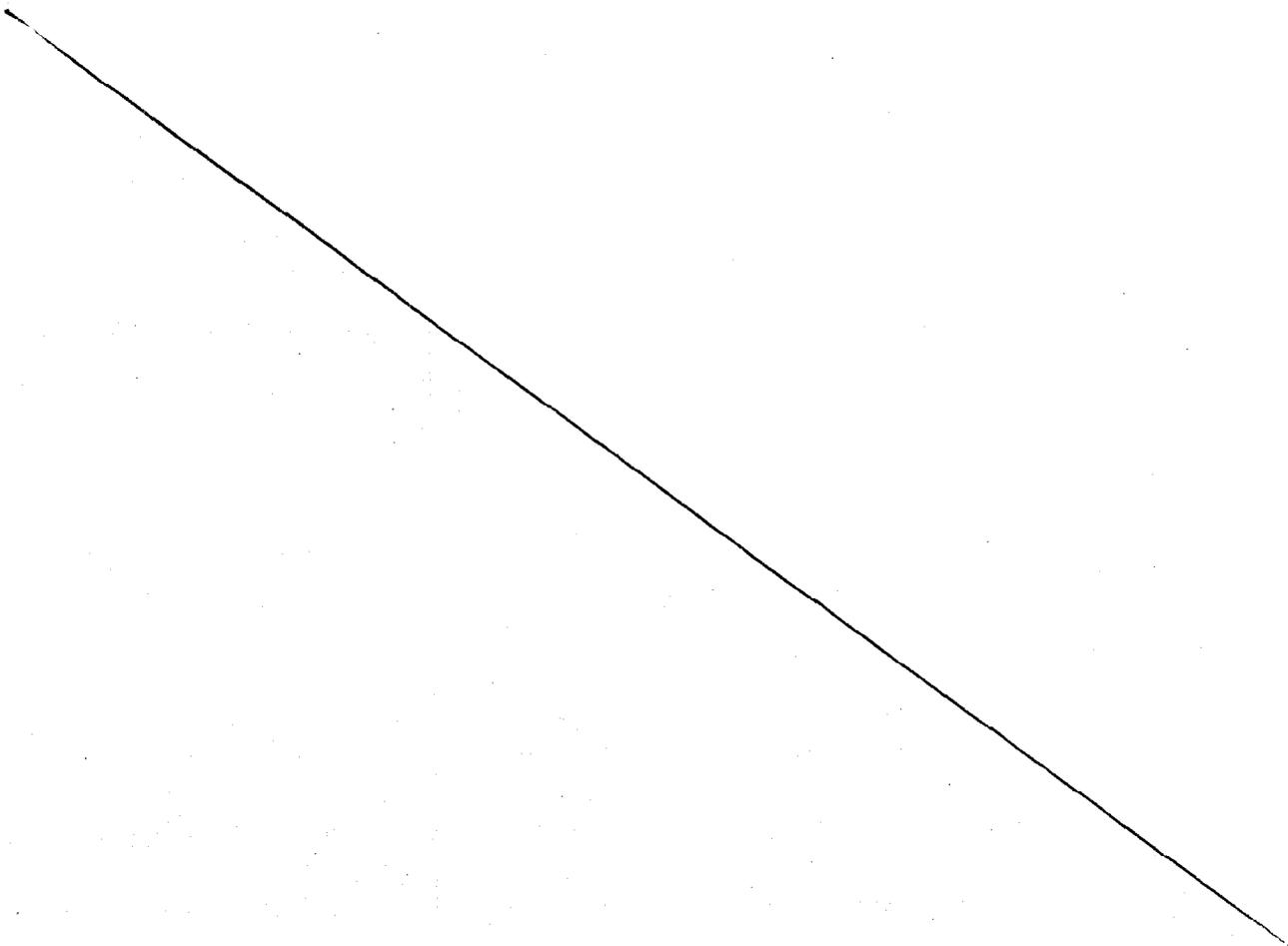
Contact Person: Nancy Chamberlin or Jaime Henriquez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or e-mail:

CHAMBERLINN@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12539 and 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 17, 2000, the committees will discuss the current status of, and future plans for, the draft FDA guidance entitled "A Guidance for Industry, Topical Dermatological Drug Product NDA's and ANDA's—In Vivo Bioavailability, Bioequivalence, In Vitro Release, and

Associated Studies;” see the FDA internet web address www.fda.gov/cder/guidance/2481dft.pdf under the heading of “Biopharmaceutics Draft Guidances.” A proposed research program for addressing scientific issues related to this guidance will also be discussed.

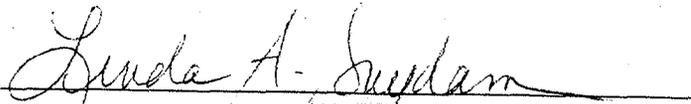
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 6, 2000. Oral presentations from the public will be scheduled between approximately 11:15 a.m. to 12:15 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: 10/11/00
October 11, 2000.


Linda A. Suydam,
Senior Associate Commissioner.

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

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