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Display Date	6-7-00
Expiration Date	6-8-00
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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). At least one portion of the meeting will be closed to the public.

Name of Committee: 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 June 29, 2000, from 8:30 a.m. to 5:30 p.m. and on June 30, 2000, from 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Tracy K. Riley or Angie Whitacre, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting. Current information may also be accessed on the Internet at the FDA Website, www.FDA.GOV.

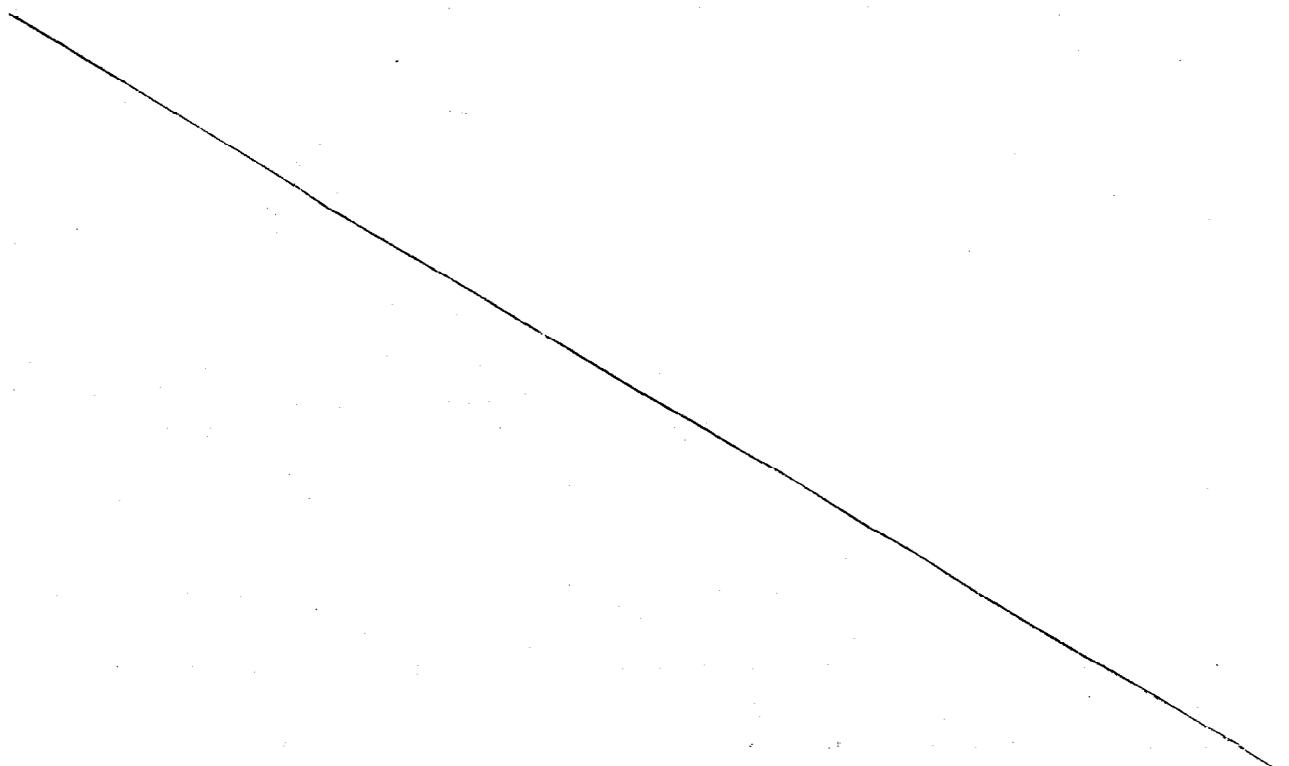
Agenda: On June 29, 2000, during the initial open session, the committee will discuss new drug application (NDA) 20-010, Lotrisone™ Lotion (clotrimazole/betamethasone dipropionate), Schering-Plough, Inc., for treatment of tinea pedis, tinea cruris, and tinea corporis; and NDA 20-996, Dermex II™ Ointment (zinc oxinate), Dermex Pharmaceuticals, Limited Liability Corp., for treatment of actinic keratosis, basal cell carcinoma, and squamous cell carcinoma. On June 30,

NMI

2000, the committee will discuss NDA 21-026, (miconazole nitrate, USP 0.25%) ointment, Johnson & Johnson Consumer Companies, Inc., for treatment of diaper dermatitis.

Procedure: On June 29, 2000, from 10 a.m. to 5:30 p.m. and on June 30, 2000, from 8:30 a.m. to 5:30 p.m., the meeting is open to the public. 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 June 21, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m. on June 29, 2000, and between approximately 8:30 a.m. and 9:30 a.m. on June 30, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 21, 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.

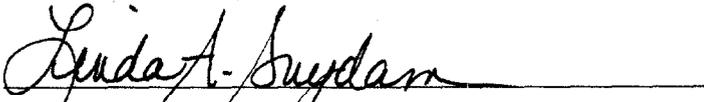
Closed Committee Deliberations: On June 29, 2000, from 8:30 a.m. to 10 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information regarding pending investigational new drug applications issues (5 U.S.C. 552b(c)(4)).



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

2).

Dated: 5/31/00
May 31, 2000



Linda A. Suydan
Senior Associate Commissioner

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

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