

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonprescription Drugs Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Nonprescription Drugs Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of March 30, 2004 (69 FR 16582). The amendment is being made to reflect changes in the introductory paragraph and in the following portions of the document: *Date and Time*, *Location*, *Agenda*, and *Procedure*; and to add a portion entitled “*Closed Committee Deliberations.*” There are no other changes.

FOR FURTHER INFORMATION CONTACT: Dornette Spell-LeSane or Kimberly Littleton Topper, 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, e-mail topperk@cder.fda.gov or spelllesaned@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area), codes 3014512541 or 3014512534. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 30, 2004, FDA announced that a meeting of the Nonprescription Drugs Advisory Committee

and the Dermatologic and Ophthalmic Drugs Advisory Committee would be held on May 6 and May 7, 2004. On page 16582, in the first and second columns, the introductory paragraph, *Date and Time*, *Location*, *Agenda*, and *Procedure* portions of the meeting notice are amended; and a portion entitled “*Closed Committee Deliberations*” is added to read as follows:

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.

Date and Time: The meeting will be held on May 6, 2004, from 8 a.m. to 5:30 p.m. and May 7, 2004, from 8 a.m. to 3:30 p.m.

Location: On May 6, 2004, from 8 a.m. to 5:30 p.m. and May 7, 2004, from 8 a.m. to 11 a.m., the committee will meet at the Center for Drug Evaluation and Research Advisory Committee Conference Room (rm. 1066), 5630 Fishers Lane, Rockville, MD. On May 7, 2004, from 11 a.m. to 3:30 p.m., the two committees will meet separately at two locations. The Nonprescription Drugs Advisory Committee will remain at the previously listed location for its separate meeting. The Dermatologic and Ophthalmic Drugs Advisory Committee will meet at the Food and Drug Administration, Parklawn Building, Chesapeake Conference Room, third floor, 5600 Fishers Lane, Rockville, MD for its separate meeting.

Agenda: On May 6, 2004, from 8 a.m. to 5:30 p.m. and May 7, 2004, from 8 a.m. to 11 a.m., the committee will discuss efficacy and labeling issues for over-the-counter drug products used in the treatment of tinea pedis (interdigital) in patients 12 years of age and over. On May 7, 2004, from 11 a.m. to 12 noon, each separate committee meeting will be open to the public, unless public participation does not last that long. From 12 noon to 3:30 p.m.,

each separate committee meeting will be closed to permit discussion and review of trade secret and/or confidential information.

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 April 23, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 6, 2004. On May 7, 2004, oral presentations from the public will be scheduled for each separate committee between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 23, 2004, 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 presentations.

Closed Committee Deliberations: On May 7, 2004, from 12 noon to 3:30 p.m., the committee meetings will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b (c)(4)).

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 15, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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