

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

*Non-Prescription Drugs Advisory Committee
in Joint Session with the
Dermatologic and Ophthalmic Drugs Advisory Committee
May 6, 2004*

AGENDA

8:00 a.m.	Call to Order and Introductions	Louis R. Cantilena, Jr., M.D., Ph.D. Chair, Nonprescription Drugs Advisory Committee, NDAC
	Conflict of Interest Statement	LCDR Dornette Spell-LeSane, MHA, NP-C Acting Executive Secretary, NDAC
	Welcome and Introductory Comments	Charles Ganley, M.D. Director, Division of Over-The -Counter Drug Products (DOTCDP), FDA

*Efficacy and labeling issues for the over-the-counter drug products used in treatment of tinea pedis
in patients 12 years of age and over*

8:15 FDA Presentation

Natural history of tinea pedis and dermatophyte infections	Joseph Porres, M.D., Ph.D. Medical Officer, DDDDP, FDA
Study design and efficacy results for tinea pedis clinical trials (Rx and OTC)	Kathleen Fritsch, Ph.D. Mathematical Statistician, Division of Biometrics III, FDA
History and overview of OTC Topical Antifungal Drug Products Monograph	Houda Mahayni, Ph.D. Interdisciplinary Scientist, DOTCDP, FDA
Topical antifungal drug product labeling	Daiva Shetty, M.D. Medical Officer, DOTCDP, FDA

10:15 Break

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*May 6, 2004
AGENDA (Cont.)*

10:30 FDA Presentation cont.

Infectious disease complications
of tinea pedis

Alan Bisno, M.D.
Professor Emeritus, University of Miami,
School of Medicine

Microbiology and dermatophyte
resistance related to the treatment of
tinea pedis

Mahmoud Ghannoum, M.Sc., Ph.D.
Director, Center for Medical Mycology and
Mycology Reference Laboratory &
Professor, Department of Dermatology,
University Hospitals of Cleveland and Case
Western Reserve University

11:30 Committee Discussions

12:00 Lunch

1:00 Open Public Hearing

2:30 Committee Discussions

3:00 Break

3:15 Committee Questions

5:30 Adjourn

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**AGENDA
May 7, 2004**

8:00 a.m.	Call to Order and Introductions	Louis R. Cantilena, Jr., M.D., Ph.D. Chair, Nonprescription Drugs Advisory Committee, NDAC
	Conflict of Interest Statement	LCDR Dornette Spell-LeSane, MHA, NP-C Acting Executive Secretary, NDAC
	Charge to the Committee	Jonathan Wilkin, M.D. Director, Division of Dermatologic and Dental Drug Products, FDA

*Efficacy and labeling issues for the over-the-counter drug products
used in treatment of tinea pedis in patients 12 years of age and over
Meeting Continued from May 6, 2004*

8:15 Committee Questions

10:45 Break

11:00 Open Public Hearing

12:00 **Closed Session**

Non-Prescription Drugs
Advisory Committee

ACS Conference Room

Dermatologic and Ophthalmic Drugs
Advisory Committee

Parklawn Bldg, "Chesapeake" Conference Room

3:30 Adjourn