

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

***Nonprescription Drugs and Dermatologic and Ophthalmic Drugs  
Advisory Committee Meeting***

***May 6, 2004***

***DRAFT 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, FDA OR Jonathan Wilkin, M.D. Director, Division of Dermatologic and Dental Drug Products, FDA

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***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, Division of Dermatologic and Dental Drug Products, FDA
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

9:45 Committee Discussion

10:15 Break

10:30 **FDA Presentation cont.**

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, Division of Over-  
The-Counter Drug Products, FDA

Topical antifungal drug product labeling

Daiva Shetty, M.D.  
Medical Officer, Division of Over-The –  
Counter Drug Products, FDA

11:30 Committee Discussion

12:00 Lunch

1:00 Open Public Hearing

2:05 Committee Discussions

3:00 Break

3:15 Committee Questions

5:30 Adjourn

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

***Nonprescription Drugs and Dermatologic and Ophthalmic Drugs  
Advisory Committee Meeting  
May 7, 2004***

***DRAFT 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
	Charge to the Committee	Charles Ganley, M.D. Director, Division of Over-The -Counter Drug Products, FDA OR Jonathan Wilkin, M.D. Director, Division of Dermatologic and Dental Drug Products, FDA

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***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  
Cont.***

8:15 Committee Questions

10:45 Break

11:00 Open Public Hearing

12:00 **Closed Session**

Division of Over-The -Counter  
Drug Products, FDA

ACS Conference Room

Division of Dermatologic and  
Dental Drug Products, FDA

Parklawn Bldg Conference Room "C"

3:30 Adjourn