

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

Nonprescription Drugs Advisory Committee (NDAC)

in joint session with the

Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC)

March 24, 2004

AGENDA

The committees will consider the safety considerations related to the switch of dermatologic corticosteroids from prescription to over-the-counter (OTC) use.

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| 8:00 | Call to Order and Introductions | Alastair Wood, M.D., Chair, NDAC |
| | Conflict of Interest Statement | LCDR Teresa A. Watkins, R.Ph.
Acting Executive Secretary, NDAC |
| 8:15 | Introduction | Charles Ganley, M.D., Division Director
Division of Over-the-Counter Drug Products |

FDA Presentations

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| 8:30 | OTC Dermatologic Topical Corticosteroids | Mike Koenig, Ph.D., Interdisciplinary Scientist
Division of Over-the-Counter Drug Products |
| 8:45 | Rx Topical Corticosteroids: HPA Axis Suppression and Cutaneous Effects | Denise Cook, M.D., Medical Officer
Division of Dermatologic and Dental Drug Products |
| 9:30 | Lessons Learned From Growth Studies with Orally Inhaled and Intranasal Corticosteroids | Stephen Wilson, Dr. P.H., CAPT USPHS
Division of Biometrics II |
| 9:45 | HPA Axis Suppression Studies: Conduct, Utility, and Pediatric Considerations | Markham Luke, M.D., Medical Team Leader
Division of Dermatologic and Dental Drug Products |
| 10:10 | Break | |
| 10:20 | Questions from the Committee and Committee Discussion | |
| 12:00 | Lunch | |
| 1:00 | Open Public Hearing | |
| 2:00 | Questions to the Committee/Summary | |
| 4:30 | Adjournment | |