



ANNUAL REPORT

OF THE

Nonprescription Drugs Advisory Committee

for the period October 1, 2003 through September 30, 2004

FUNCTION

The Committee shall review and evaluate available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advise the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee will serve as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

MEMBERSHIP

See attached Roster

MEETINGS

The committee met 3 times during the reporting period in Gaithersburg, Maryland and in Rockville, Maryland.

The dates of the meetings were: December 16, 2003, May 6-7, 2004, and May 7, 2004.

The meeting on May 7, 2004 included a closed session to permit discussion or presentation of trade secret or confidential commercial information or disclosure would constitute a clearly unwarranted invasion of personal privacy.

ACCOMPLISHMENTS

The activities of the committee during this meeting included:

On December 16, 2004, the Committee met in joint session with the Reproductive Health Drugs Advisory Committee to discuss the proposed over-the-counter (OTC) use of Plan B (levonorgestrel), Women's Capitol Corporation, for reducing the chance of pregnancy after unprotected sex. The Committee voted in favor of approval of the application. On May 6, 2004, the Agency issued a Not Approvable letter for Plan B.

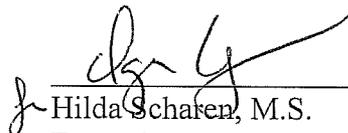
On May 6 and 7, 2004 the Committee met in joint session with the with the Dermatologic and Ophthalmic Drugs Advisory Committee to discuss efficacy and labeling issues for over-the-counter drug products used in the treatment of tinea pedis (interdigital) in patients 12 years of age and over. Recommendations were made concerning the lowest acceptable rate of cure that is clinically meaningful for a topical drug product for the treatment of tinea pedis, labeling, and drug development protocols.

Detailed information related to these open sessions is available in the annual report.

At the closed session of the May 7, 2004 meeting, the Division of Over-the-Counter Drug Products provided the Committee with an update on past matters and upcoming issues. No advice was sought of the Committee. The meeting was closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c) (4)).

09/30/2004

Date



Hilda Scharen, M.S.
Executive Secretary

**NONPRESCRIPTION DRUGS ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH**

Chair

Louis R. Cantilena, Jr., M.D., Ph.D.

Expertise: Clinical Pharmacology

Term: 06/01/00 - 05/31/04

Director, Division of Clinical Pharmacology
and Medical Toxicology

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Expertise: Industry Representative

Term: 02/02/04 - 10/31/07

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Neal L. Benowitz, M.D.

Expertise: Clinical Pharmacology, Poison Control

Term: 09/25/03 - 05/31/06

Chief, Division of Clinical Pharmacology

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Terrence F. Blaschke, M.D.

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Term: 09/25/03 - 05/31/07

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Term: 08/20/01 - 05/31/05

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Expertise: Pharmacy Practice

Term: 09/25/03 - 05/31/07

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College of Pharmacy

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Term: 06/01/00 - 05/31/04

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* Consumer Representative

** Industry Representative