



ANNUAL REPORT
OF THE
Dermatologic and Ophthalmic Drugs Advisory Committee
for the period
October 1, 2003 through September 30, 2004

FUNCTION

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disease states and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met four times during the reporting period in Rockville and Bethesda, Maryland.

The dates of those meetings were February 26 & 27, 2004, May 6 & 7, 2004, July 12, 2004 and August 27, 2004.

The meeting on May 7, 2004 included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending and future issues within the Review Division.

ACCOMPLISHMENTS

February 26, 2004: Effectiveness of the isotretinoin risk management program for the prevention of fetal exposure to Accutane and its generic equivalents and consideration of whether changes to this isotretinoin risk management program would be appropriate. A new Risk Management Plan was developed and is in the process of implementation.

May 6 & 7, 2004: The committee discussed NDA 21-662, LAMISIL AT Spray Powder, 1% (terbinafine hydrochloride), Novartis Consumer Health, Inc. for the Over-the-Counter treatment of tinea pedis (interdigital) and tinea cruris in patients 12 years of age and over. On May 7th, the committee held a closed session to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c) (4)). The issue is under consideration by FDA.

July 12, 2004: The committee discussed oral tazarotene 1.5mg and 4.5 mg capsules (proposed trade name Tazorol), Allergan, Inc., proposed for the treatment of moderate to severe psoriasis, including risk management options to prevent fetal exposure. The issue is under consideration by FDA.

August 27, 2004: The committee discussed pegaptanib sodium injection (proposed trade name is Macugen) by Eyetech Pharmaceuticals, Inc., indicated for the treatment of exudative (wet) age-related macular degeneration. The information gathered is still under consideration. The issue is under consideration by FDA.

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

09/30/2004
Date



Kimberly Littleton Popper
Executive Secretary

Dermatologic and Ophthalmic Drugs Advisory Committee

Chairman

Roselyn E. Epps, M.D.

Expertise: Pediatric Dermatology

Term: 08/20/01 - 08/31/04

Section Head

Pediatric Dermatology

Children's National Medical Center

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Jennifer Dunbar, M.D.

Expertise: Ophthalmology

Term: 06/23/03 - 08/31/06

Loma Linda University

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William Gates, M.D.

Expertise: Ophthalmology

Term: 06/23/03 - 08/31/06

Summit Eye Associates, P.C.

5653 Frist Blvd, Suite 532

Hermitage, Tennessee 37076

Robert Katz, M.D.

Expertise: Dermatology

Term: 03/25/02 - 08/31/05

Dermatology Clinic

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Executive Secretary

Kimberly Littleton Topper, M.S.

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***Paula Knudson**

Expertise: Consumer Representative

Term: 03/25/02 - 08/31/05

Executive Coordinator of IRB

Research and Academic Affairs

The University of Texas

Houston Health Science Center

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****Peter A. Kresel, M.B.A.**

Expertise: Industry Representative

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

Senior Vice President

Global Regulatory Affairs

Allergan

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William B. Phillips, II, M.D.

Expertise: Ophthalmology

Term: 06/23/03 - 08/31/06

The Retina Group of Washington, P.C.

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Sharon S. Raimer, M.D.

Expertise: Pediatric Dermatology

Term: 03/25/02 - 08/31/05

Professor and Chairman

Department of Dermatology

University of Texas Medical Branch

Galveston, Texas 77550-0783

Eileen W. Ringel, M.D.

Expertise: Dermatology

Term: 12/22/03 - 08/31/06

Dermatologist

Private Practice

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Kathleen Y. Sawada, M.D.

Expertise: Dermatology

Term: 03/25/02 - 08/31/05

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Laser Institute PLLC

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Expertise: Dermatology

Term: 12/22/03 - 08/31/07

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Robert S. Stern, M.D.

Expertise: Dermatology

Term: 03/22/99 - 08/31/04

Beth Israel Deaconess Medical Center

330 Brookline Avenue

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Thomas R. Ten Have, Ph.D.

Expertise: Statistics

Term: 12/22/03 - 08/31/06

Associate Professor

Department of Biostatistics and

Clinical Epidemiology

University of Pennsylvania

School of Medicine

607 Blockley Hall

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Philadelphia, Pennsylvania 19104-6021

William Tasman, M.D.

Expertise: Ophthalmology

Term: 03/25/02 - 08/31/05

Professor and Chairman

Department of Ophthalmology

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Elizabeth S. Whitmore, M.D.

Expertise: Dermatology

Term: 12/22/03 - 08/31/06

Private Practice

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Michael G. Wilkerson, M.D.

Expertise: Dermatology

Term: 12/22/03 - 08/31/06

Hillcrest Medical Group

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* Consumer Representative

** Industry Representative