

**Food and Drug Administration
Center for Drug Evaluation and Research (CDER)**

Arthritis Advisory Committee (AAC)

June 2, 2004

ACS Conference Room, Room 1066
5630 Fishers Lane, Rockville, MD

AGENDA

Issue: Trial Design and Endpoints for Drugs for Chronic Gout

8:00	Call to Order and Opening Remarks Introductions	Allan Gibofsky, M.D., J.D. Chair, AAC
	Conflict of Interest Statement	Jayne E. Peterson, R.Ph., J.D. Acting Executive Secretary, AAC, FDA
8:15	Welcome	Brian E. Harvey, M.D., Ph.D. Acting Director, Div. of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products (DAAODP), FDA
	Uric Acid and Gout	James P. Witter, M.D., Ph.D.
8:45	Gout: An Evolving Problem at a Therapeutic Crossroads	Robert A. Terkeltaub, M.D. Chief, VAMC Rheumatology Section Professor of Medicine in Residence University of California, San Diego
9:30	Cardiome Pharma, Inc. Introduction	Alan Moore, Ph.D. Executive Vice President, Clinical Development and Reg. Affairs
	Gout: a Serious Progressive Disease	Ralph Snyderman, M.D. Chancellor for Health Affairs, Duke Univ. President/CEO, Duke Univ. Health System
	Oxypurinol Efficacy and Safety	Garth Dickinson, M.D. Depts. of Medicine and Emerg. Medicine University of Ottawa
	OXPL213 Analysis	Robert W. Makuch, Ph.D. Professor and Head, Biostatistics Dept. of Epidemiology and Public Health Yale University School of Medicine
	Unmet Medical Need/Clinical Experience and Post-Approval Issues	Leonard Calabrese, D.O. Vice Chair, Dept. of Rheumatic and Immunologic Diseases Head, Section of Clinical Immunology RJ Fasenmyer Chair of Clin. Immunology Cleveland Clinic Foundation

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AGENDA (cont.)

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10:30 Break

10:45 Oxypurinol, Treatment of Symptomatic
Gout in Allopurinol Intolerant Patients

Lourdes Villalba, M.D.
Medical Officer, DAAODP, FDA

11:30 Lunch

1:00 Open Public Hearing

2:00 Committee Discussion and Questions

3:15 Break

5:00 Adjourn

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Meeting Participants

Special Government Employee (SGE) Consultants (Voting)

H. James Williams, M.D.

Professor of Medicine, Dept. of Internal Medicine
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Brian F. Mandell, M.D., Ph.D.

Clinical Professor of Medicine
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David T. Felson, M.D., MPH

Professor of Medicine and Public Health
School of Medicine, Boston University
80 East Concord Street, A 201
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Government Employee Participants/Discussants (Voting)

Marc C. Hochberg, M.D., MPH

Professor of Medicine
Head, Div. of Rheumatology and
Clinical Immunology
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22 South Greene Street
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Government Employee Speaker (Non-Voting)

Robert Terkeltaub, M.D.

Chief, VAMC Rheumatology Section
Professor of Medicine in Residence, UCSD
Director, UCSD Rheumatology Training Program
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