

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

Arthritis Advisory Committee (AAC)

June 3, 2004

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

AGENDA

Issue: Trial Design and Endpoints for Drugs for Acute 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
	Introduction and Overview of the Topic	Joel Schiffenbauer, M.D.
8:45	Background and Scientific Status	John J. Cush, M.D.
9:30	Merck Research Laboratories Introduction	Agustin Melian, M.D. Director, Clinical Research Merck Research Laboratories
	Design Considerations in Acute Gouty Arthritis Studies	David I. Daikh, M.D., Ph.D. Assistant Professor of Medicine University of California at San Francisco Staff Physician San Francisco VA Medical Center
	Experience of Etoricoxib and Indomethacin In Acute Gouty Arthritis	Agustin Melian, M.D.
	Lessons Learned	David I. Daikh, M.D., Ph.D.
10:30	Break	
10:45	Discussion	
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)

Michael H. Weisman, M.D.
Professor of Clinical Medicine
UCLA
Director, Div. of Rheumatology
Dept. of Medicine
Cedars-Sinai Medical Center
8700 Beverly Blvd., B-131
Los Angeles, California 90048

H. James Williams, M.D.
Professor of Medicine
Dept. of Internal Medicine
Div. of Rheumatology
University of Utah
50 North Medicine Drive
Salt Lake City, Utah 84132

Brian F. Mandell, M.D., Ph.D.
Clinical Professor of Medicine
Penn State Hershey School of Medicine
Cleveland Clinic, Div. of Medicine
Dept. of Rheumatology
9500 Euclid Ave., A50
Cleveland, Ohio 44195

Bruce N. Cronstein, M.D.
Professor of Medicine and Pathology
NYU Medical Center
Department of Medicine
Division of Rheumatology
550 First Avenue
New York, New York 10016

Government Employee Participants/Discussants (Voting)

Robert Terkeltaub, M.D.
Chief, VAMC Rheumatology Section
Professor of Medicine in Residence, UCSD
Director, UCSD Rheumatology Training Program
Associate Division Director, UCSD Rheumatology
Allergy-Immunology Division
VAMC, 1111-K, 3350 La Jolla
Village Drive
San Diego, California 02161

Marc C. Hochberg, M.D., MPH
Professor of Medicine
Head, Division of Rheumatology and
Clinical Immunology
School of Medicine
University of Maryland
22 South Greene Street
Baltimore, Maryland 21201

H. Ralph Schumacher, M.D.
Professor of Medicine, Division of Rheumatology
University of Pennsylvania, School of Medicine
VA Medical Center
University and Woodland Avenue
Philadelphia, Pennsylvania 19104