

Food and Drug Administration
Center for Drug Evaluation and Research

**SUMMARY MINUTES
ARTHRITIS ADVISORY COMMITTEE**

August 17, 2001
Gaithersburg Holiday Inn
2 Montgomery Village Avenue, Gaithersburg, MD

Members Present

Ildy M. Katona, M.D. CAPT, MC, USN
H. James Williams, Jr., M.D.
Jennifer Anderson, Ph.D.
Leigh F. Callahan, Ph.D.

FDA Participants

William D. Schwieterman, M.D.
M. Miles Braun, M.D., M.P.H.
Jong-Hoon Lee, M.D.
Jeffrey N. Siegel, M.D.
Jay Siegel, M.D.

Consultants

Steven B. Abramson, M.D.
Janet D. Elashoff, Ph.D.
Leona M. Malone, M.S.W
David Wofsy, M.D.
Michael F. Iademarco, M.D., M.P.H.
Joseph Keane, M.D.
Julie M. Vose, M.D.

Guest Experts

Members Absent

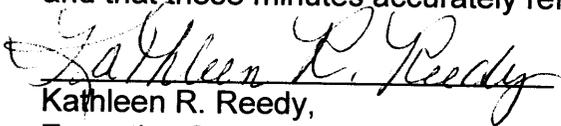
David Yocum, M.D.
Yvonne Sherrer, M.D.
Gary Firestein, M.D.
Wendy McBair, R.N., M.S.
Kenneth Brandt, M.D.
E. Nigel Harris, M.D.

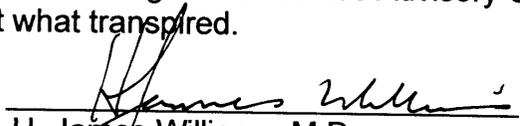
Executive Secretary

Kathleen R. Reedy, RDH, MS

These summary minutes for the August 17, 2001 meeting of the Arthritis Advisory Committee were approved on 9-21-01.

I certify that I attended the August 17, 2001 meeting of the Arthritis Advisory Committee and that these minutes accurately reflect what transpired.


Kathleen R. Reedy,
Executive Secretary


H. James Williams, M.D.
Chairperson

The Arthritis Advisory Committee met on August 17, 2001 at the Gaithersburg Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, MD, Whetstone, Walker and Goshen rooms, to hear end of Phase 4 studies Safety Updates on Enbrel™ (etanercept), Immunex, and Remicade™ (infliximab) Centocor from both the FDA/CBER and the sponsors. There were approximately 250 people in the audience. The committee had been provided with briefing documents from the sponsors and the FDA four weeks before the meeting.

The meeting was called to order by H. James Williams, M.D., Acting Chair at 10:00 am. The Meeting Statement was read by Kathleen Reedy, Executive Secretary.

The FDA, CBER Presentation consisted of:

Objectives: William D. Schwieterman, M.D., Branch Chief

MedWatch Adverse Event Data: Value & Limitations: M. Miles Braun, M.D., M.P.H.
Director, Division of Epidemiology, Office of Biostatistics and Epidemiology

Safety Data: Jong-Hoon Lee, M.D., Medical Reviewer

Division of Epidemiology, Office of Biostatistics and Epidemiology

Jeffrey N. Siegel, M.D., Medical Reviewer

Division of Clinical Trial Design and Analysis

Office of Therapeutics Research and Review

Speakers at the Open Public Hearing included:

Judith Levenson, patient

Joan London, patient and a MD Chapter of the Arthritis Foundation Board Member

Elizabeth Bachorik, patient

Carl Lowe, patient

The Immunex Presentation:

Etanercept Post-Marketing Surveillance: Daniel Burge, M.D.

Safety Data, Epidemiology and Communications: Wayne Wallis, M.D.

Pharmacovigilance Program: Daniel Burge, M.D.

The Centocor Presentation:

Introduction and Background: Jerry Boscia, M.D., Vice President, Clinical R&D

Communication Plan and Continuing Safety Assessment: Tom Schaible, Ph.D.,
Executive Director, Medical Affairs

Benefit/Risk: Jerry Boscia, M.D., Vice President, Clinical R&D, Centocor

The Committee asked questions of the sponsors and of the FDA, CBER Division and there was some discussion. Committee members and public speakers thanked the FDA for bringing this safety update and end of phase 4 report of adverse events and labeling changes to the Advisory Committee in a public forum. The Sponsors voiced their appreciation for being invited to participate and present.

The meeting was adjourned at 2:00.

Kathleen Reedy, RDH, MS, Health Scientist Administrator
Executive Secretary, Arthritis Advisory Committee