

Food and Drug Administration
Center for Drug Evaluation and Research

**SUMMARY MINUTES
ARTHRITIS ADVISORY COMMITTEE**

February 5, 1997
Gaithersburg Hilton
620 Perry Parkway, Gaithersburg, MD

Members Present

Michelle Petri M.D., M.P.H., Chair
Steven B. Abramson, M.D.
Barbara C. Tilley, Ph.D.
Leona Malone, MSW
Frank Pucino, Jr., Pharm.D.
Daniel J. Lovell, M.D., M.P.H.
Matthew Liang, M.D., M.P.H.
David Felson, M.D., M.P.H.
Lee Simon, M.D.
Harvinder Luthra, M.D.
Felix Fernandez-Madrid, M.D., Ph.D.

FDA Participants

Wiley A. Chambers, M.D.
Kent Johnson, M.D.

Consultants

Karyl S. Barron, M.D.
M. Clinton Miller, Ph.D.
Patience H. White, M.D.

Guest Experts

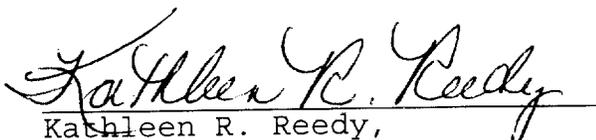
Members Absent

Executive Secretary

Kathleen R. Reedy

These summary minutes for the February 5, 1997 meeting of the Arthritis Advisory Committee were approved on 4/4/99.

I certify that I attended the February 5, 1997 meeting of the Arthritis Advisory Committee and that these minutes accurately reflect what transpired.


Kathleen R. Reedy,
Executive Secretary


Michelle A. Petri, M.D., M.P.H.
Chairperson

The Arthritis Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research met at the Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD. on February 5, 1997 to discuss the content of a document, "Guidance for Industry in Designing Clinical Programs for Developing Drugs, Devices or Biological Products Intended for the Treatment of Rheumatoid Arthritis (RA)." The Committee had been provided with the most recent draft of the document as background in preparation for the meeting. Approximately 120 people attended the meeting.

The meeting was called to order at 8:00 am by Michelle Petri, M.D., M.P.H. Chairperson of the Arthritis Advisory Committee, and began with the introduction of those present at the discussion table. The meeting statement regarding conflict of interest was read by Kathleen Reedy, Executive Secretary, followed by welcoming comments by Wiley A. Chambers, M.D., Acting Director of the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products. There were no speakers at the Open Public Hearing.

Introduction to the Document was presented by Kent R. Johnson, M.D., Medical Officer in the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products. There was discussion of adult claims, centered around major clinical response and the use and definition of drug products; the quality of life, and the duration of trials.

The next discussion topic was Statistical Considerations, in particular equivalency standards and dropout design addendum.

The afternoon discussion was dedicated to JRA Claims and Questions. The eligibility of JRA patients for trials was the first area examined. The inclusion of subsets and inferences drawn was explored covering the aspects of Phase 4 studies, safety issues and registries.

A verbatim transcript is available for perusal of the specifics and consensus of the discussion.

The meeting was adjourned at 5:00 pm.