Food and Drug Administration
Center for Drug Evaluation and Research

SUMMARY MINUTES
ARTHRITIS ADVISORY COMMITTEE

May 7, 1996
Holiday Inn Gaithersburg
2 Montgomery Village Avenue, Gaithersburg, MD

Members Present
George Ehrlich, M.D., Chair
Michelle Petri M.D., M.P.H.
David Felson, M.D., M.P.H.
Harvinder S. Luthra, M.D.
Lee Simon, M.D.
Felix Fernandez-Madrid
Daniel Lovell, M.D., M.P.H.

FDA Participants
Janet Woodcock, M.D.
Shaw Chen, M.D., Ph.D.
Leo Lutwak, M.D., Ph.D.
Juan Carlos Pelayo, M.D.
Wiley Chambers, M.D.
Michael Weintraub, M.D.

Guest Experts
Harlan E. Ives, M.D., Ph.D.
Robert M. Neer, M.D.
Hartmut H. Malluche, M.D.

Consultants
Leona M. Malone, MSW

Members Absent
Matthew H. Liang, M.D., M.P.H.
Steven B. Abramson, M.D.

Executive Secretary
Kathleen R. Reedy

These summary minutes for the May 7, 1996 meeting of the Arthritis Advisory Committee were approved on 6/4/99.

I certify that I attended the May 7, 1996 meeting of the Arthritis Advisory Committee and that these minutes accurately reflect what transpired.

Kathleen R. Reedy,
Executive Secretary

George Ehrlich, M.D.
Chairperson

Food and Drug Administration
Center for Drug Evaluation and Research

SUMMARY MINUTES
ARTHRITIS ADVISORY COMMITTEE

May 7, 1996
Holiday Inn Gaithersburg
2 Montgomery Village Avenue, Gaithersburg, MD

Members Present
George Ehrlich, M.D., Chair
Michelle Petri M.D., M.P.H.
David Felson, M.D., M.P.H.
Harvinder S. Luthra, M.D.
Lee Simon, M.D.
Felix Fernandez-Madrid, M.D.,Ph.D
Daniel Lovell, M.D., M.P.H.

FDA Participants
Janet Woodcock, M.D.
Shaw Chen, M.D., Ph.D.
Leo Lutwak, M.D., Ph.D.
Juan Carlos Pelayo, M.D.
Wiley Chambers, M.D.
Michael Weintraub, M.D.

Consultants
Leona M. Malone, MSW

Guest Experts
Harlan E. Ives, M.D., Ph.D.
Robert M. Neer, M.D.
Hartmut H. Malluche, M.D.

Members Absent
Matthew H. Liang, M.D., M.P.H.
Steven B. Abramson, M.D.

Executive Secretary
Kathleen R. Reedy

These summary minutes for the May 7, 1996 meeting of the Arthritis Advisory Committee were approved on _____.

I certify that I attended the May 7, 1996 meeting of the Arthritis Advisory Committee and that these minutes accurately reflect what transpired.

Kathleen R. Reedy,
Executive Secretary

George Ehrlich, M.D.
Chairperson

The Arthritis Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research met on May 7, 1996 at the Holiday Inn Gaithersburg, 2 Montgomery Village Avenue, Gaithersburg, MD to hear presentations and discuss data submitted regarding the safety and efficacy of NDA 20-395, Enable® (tenidap sodium) Pfizer, Inc., for use in the treatment of rheumatoid arthritis and osteoarthritis. The Open Session was attended by approximately 200 persons. The Advisory Committee members and guest experts had been provided a background document from both the sponsor and reviews from the Agency approximately 20 days before the meeting.

At 8:00 am the meeting was called to order by George Ehrlich, M.D., Chair of the Arthritis Advisory Committee, and introductions of the participants at the head table were conducted. The Conflict of Interest Statement for the meeting was read by Kathleen Reedy, Executive Secretary of the Arthritis Advisory Committee.

No one had registered to speak at the open public hearing.

The Sponsor Presentation included:

Introduction: Jeffery Stritar, M.D., Ph.D., Pfizer Central Research
Enable® Efficacy: Jeffery Stritar, M.D., Ph.D., Pfizer Central Research
Enable® Safety: Ethan Weiner, M.D., Pfizer Central Research
Enable® Risk/Benefit: Warren Blackburn, M.D., University of Alabama

The FDA Presentation followed:
Efficacy: Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research
Safety: Shaw Chen, M.D., Ph.D., Division of Cardiovascular and Renal Drug Products
Renal: Juan Carlos Pelayo, M.D., Division of Cardiovascular and Renal Drug Products
Bone: Leo Lutwak, M.D., Ph.D., Division of Metabolism and Endocrine Drug Products
Conclusion: Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research

The discussion followed.. Guest experts Robert M. Neer, M.D. of Massachusetts General Hospital commented on concerns with bone mineral density effects. Both Harlan E. Ives, M.D., Ph.D. of University of California San Francisco and Hartmut H. Malluche, M.D. of University of Kentucky Medical Center discussed concerns with renal effects. Committee members and guest experts discussed the safety issues concerning renal, bone mineral density and hepatic effects of the drug at recommended dosage.

The Questions were addressed and the consensus is documented.

1. Has an acceptable benefit/risk ratio been demonstrated for tenidap in the treatment of OA?

Yes: 1 No: 7

A. Should the drug be approved for OA? Not addressed due to response to 1.

2. Has an acceptable benefit/risk ratio been demonstrated for tenidap in the treatment of RA?

Yes: 0 No: 7 Abstain: 1

A. Should the drug be approved for RA? Not addressed due to response to 2.

The remaining questions were not addressed as they hinged on recommendation for approval.

If yes, please comment on the labeling claims that should be included.

3. If approval is recommended, please comment on:
   A. Safety labeling with respect to renal effects.
   B. Safety labeling with respect to potential effects on bone.

The meeting was adjourned at approximately 3:15 pm.

Kathleen Reedy, Executive Secretary, Arthritis Advisory Committee