FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

ARTHRITIS ADVISORY COMMITTEE (AAC) MEETING JUNE 23-24, 2003

AGENDA

Versailles Ballroom, Holiday Inn, Bethesda, MD

June	23	200	13
June	43.	200	,,

8:00 a.m. Call to Order Gary S. Firestien, M.D.

Chair, AAC

Introduction of Committee

Conflict of Interest Statement Johanna Clifford, M.S., RN, BSN

Acting Executive Secretary, AAC

8:15 a.m. **Opening Remarks**

Discussion of Fibrolmyalgia, clinical trial design, including important disease endpoints, in the study and development therapies and treatments.

Historical Background of Fibromyalgia

8:45 a.m. Pre ACR Diagnostic Criteria

9:15 a.m. Basic Mechanisms

9:45 a.m. Post ACR Diagnostic Criteria

10:30 a.m. *Break*

10:45 a.m. A Patient's Perspective

11:00 a.m. Outcomes: Multi-System Impact

11: 30 Open Public Hearing

12:00 p.m. *Lunch*

1:00 p.m. Charge to Committee

1:30 p.m. Committee Discussion and Response to FDA Questions

2:30 p.m. *Break*

4:30 p.m. Adjourn

June 24, 2003

8:00 a.m. Call to Order Howard J. Williams, M.D.

Acting Chair, AAC

Introduction of Committee

Conflict of Interest Statement Johanna Clifford, M.S., RN, BSN

Acting Executive Secretary, AAC

Discussion of Enbrel (etanercept) indicated for reducing the signs and symptoms of ankylosing spondylitis.

8:15 a.m. **Amgen Presentation** Introduction **Assessments in Ankylosing Spondylitis Clinical Program and Results Benefit/Risk Assessment** 9:15 am. Questions from the Committee Sponsor 9:45 a.m. Break10:00 a.m. **FDA Presentation** Questions from the Committee to FDA 11:00 a.m. 11:30 a.m. Open Public Hearing 12:00 p.m. LunchCommittee Discussion and Response to FDA Questions 1:00 p.m. 2:00 p.m. Break 2:15 p.m. Continuation of Committee Discussion and Response to FDA Questions

4:30 p.m.

Adjourn