## 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, 2003

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. $\quad$ 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.
10:00 a.m. FDA Presentation
11:00 a.m. Questions from the Committee to FDA
11:30 a.m. Open Public Hearing
12:00 p.m. Lunch
1:00 p.m. Committee Discussion and Response to FDA Questions
2:00 p.m. Break

2:15 p.m. Continuation of Committee Discussion and Response to FDA Questions
4:30 p.m. Adjourn

