

**Food and Drug Administration
Center for Drug Evaluation and Research**

**Arthritis Advisory Committee
Gaithersburg Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, MD**

**Agenda
August 17, 2001**

**Safety Updates:
Enbrel™ (etanercept), Immunex,
Remicade™ (infliximab) Centocor**

10:00 Call to Order and Introductions: H. James Williams, M.D., Acting Chair
Meeting Statement: Kathleen Reedy, Executive Secretary

10:15 FDA, CBER Presentation:

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

11:15 Open Public Hearing

11:45 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.

12:15 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

12:45 Break

1:00 Questions and Discussion

2:00 Adjourn