

Arthritis Advisory Committee
Food and Drug Administration
Center for Drug Evaluation and Research

July 12, 2000

Holiday Inn Gaithersburg, 2 Montgomery Village Avenue, Gaithersburg, MD

BLA 99-1234, RemicadeJ (infliximab) Centocor

Agenda

- 8:00** Call to Order, Introductions: Lee S. Simon, M.D., Acting Chair,
Arthritis Advisory Committee
Meeting Statement: Kathleen Reedy, Executive Secretary,
Arthritis Advisory Committee
- 8:15 Centocor Presentation**
Introduction: Martin Page, VP Worldwide Regulatory Affairs, Centocor, Inc.
Scientific Rationale and Clinical Pharmacology: Professor Ravinder Maini, M.D., FRCP;
Kennedy Institute of Rheumatology, London, UK
Efficacy and Safety: Gregory Harriman, M.D.; Senior Director,
Immunology Clinical Research, Centocor, Inc.
Significance of Radiographic Results: Desiree M.F.M. van der Heijde, M.D., Ph.D.;
Professor of Rheumatology, University Hospital Maastricht, The Netherlands
Clinical Perspective: E. William St. Clair, M.D.; Associate Professor of Medicine;
Duke University School of Medicine, Durham, North Carolina
Conclusion: Martin Page, VP Worldwide Regulatory Affairs, Centocor, Inc.
- 9:15 FDA, CBER Presentation**
Barbara Matthews, M.D., Medical Officer
George Mills, M.D., Medical Officer
Division of Clinical Trial Design and Analysis
Office of Therapeutics Research and Review, CBER
- 10:15 Break**
- 10:30 Open Public Hearing**
Mary Armitage, patient
Regina VanDervort, patient
- 11:00 Lunch**
- 12:00 Discussion and Questions**
- 2:30 General Issues Discussion: Claims based on Radiographic Data**
Radiographic Analyses of Disease Progression: Vibeke Strand, M.D.,
Clinical Associate Professor, Division of Immunology, Stanford University
- 5:00 Adjourn**

