

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

August 7, 1998

Holiday Inn Bethesda
8120 Wisconsin Avenue, Bethesda, MD
NDA 20-905, leflunomide, Hoechst Marion Roussel

Agenda

- 8:00** Call to Order, Introductions: Michelle Petri, M.D., Chair
Arthritis Advisory Committee
Meeting Statement: Kathleen Reedy, Executive Secretary
Arthritis Advisory Committee
- 8:30** **Hoechst Marion Roussel, Inc. Presentation**
Introduction: Elaine Waller, Pharm.D.
Vice President, North American Drug Regulatory Affairs, HMR
Preclinical/Pharmacokinetics: Mark Eller, Ph.D.
Senior Director, Biodynamics, HMR
Clinical Efficacy: Vibeke Strand, M.D., FACP
Clinical Associate Professor, Division of Immunology
Stanford University
Clinical Safety: Iris Loew-Friedrich, M.D., Vice President
Product Realization, Head of Global Clinical Management, HMR
Clinical Comment: Marc Hochberg, M.D., Professor of Medicine
Head of the Division for Rheumatology and Clinical Immunology
University of Maryland
Concluding Remarks: Elaine Waller, Pharm.D.
- 10:00** **Break**
- 10:15** **FDA Presentation**
Medical: Kent Johnson, M.D., Medical Officer
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drugs
Statistics: Laura Lu, Ph.D., Division of Biometrics IV,
Office of Epidemiology and Biostatistics
Pharmacology: Asoke Mukherjee, Ph.D.,
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drugs
Pharmacokinetics: Veneeta Tandon, Ph.D.,
Division of Pharmaceutical Evaluation III ,
Office of Clinical Pharmacology and Biopharmaceutics
- 11:15** **Open Public Hearing**
- 12:15** **Lunch**
- 1:15** **Discussion and Questions**
- 3:00** **Break**
- 5:00** **Adjourn**