

Food and Drug Administration
Center for Drug Evaluation and Research
Arthritis Advisory Committee
Silver Spring Holiday Inn, 8777 Georgia Avenue, Silver Spring, MD

Agenda
March 5, 2003

NDA: 20-905, **ARAVA™, (leflunomide), Aventis Pharmaceuticals Inc.**

- 8:00 Call to Order and Introductions:** Steven B. Abramson,, M.D., Acting Chair
Meeting Statement: Kathleen Reedy, Executive Secretary
Welcome: Lee S. Simon, M.D., Director, Division of Antinflammatory, Analgesic
and Ophthalmologic Drug Products
- 8:15 Open Public Hearing**
- 9:00 Regulatory History: Arava and Treatment of Rheumatoid Arthritis:**
Lee S. Simon, M.D.
- 9:25 Health Assessment Questionnaire:** James F. Fries, M.D., Stanford
University
- 9:50 Break**
- 10:10 Aventis Presentation: Efficacy:** Michael Rozycki, Ph.D.
Joseph Doyle, R.PH., MBA.
Karen Simpson, M.D.
- 10:55 Statistics:** Suktae Choi, Ph.D., FDA
- 11:05 Discussion and Questions: Efficacy**
- 12:00 Lunch**
- 1:00 Open Public Hearing (if needed)**
- 1:00 FDA Presentation: Safety:** Lawrence Goldkind, M.D., FDA
- 2:00 Aventis Presentation: Safety:** Michael Rozycki, Ph.D.
William Holden, M.D.
Vibeke Strand, M.D.
- 2:45 Break**
- 3:00 Discussion of labeling rare serious events:** Ruth Day, Ph.D., Duke University
- 3:30 Discussion and Questions: Safety**
- 5:00 Adjourn**