

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

Arthritis Advisory Committee

**CDER Advisory Committee Conference Room
5630 Fishers Lane, Room 1066, Rockville, MD**

**Agenda
April 19, 2001**

NDA # 21-239 ASLERA™ (prasterone, Genelabs Technologies, Inc.)

- 8:00 Call to Order and Introductions: E. Nigel Harris, M.D., Acting Chair
Meeting Statement: Kathleen Reedy, Executive Secretary**
- 8:15 Welcome and Introduction: Jonca C. Bull, M.D., Acting Director
Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products
Regulatory Background: Kent R. Johnson, M.D., Medical Officer, DAAODP**
- 8:30 Genelabs Technologies Inc. Presentation**
Overview: Marc Gurwith, MD, JD, Vice President, Drug Development,
Chief Medical Officer, Genelabs Technologies, Inc.
Introduction: Robert Lahita, MD, PhD, Professor of Medicine,
Saint Vincent's Medical Center
Summary of Efficacy: Michelle Petri, MD, MPH, Associate Professor of Medicine
Johns Hopkins Medical Center
Clinical Perspective: Murray Urowitz, MD, FRCPC, Professor of Medicine
University of Toronto
- 10:00 Break**
- 10:15 FDA Presentation**
Pharmacology/Toxicology: Susan Wilson, D.V.M. , Ph.D.
Clinical Pharmacology: Abimbola Adebowale, Ph.D.
Medical: Kent R. Johnson, M.D.
Statistical: Laura Lu, Ph.D.
- 11:15 Open Public Hearing**
- 11:45 Lunch**
- 1:00 Discussion and Questions:**
- 3:30 Summary and Review**
- 4:00 Adjourn**