

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

**Arthritis Advisory Committee**

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

**(Draft) Agenda  
February 8, 2001**

**NDA # 21-042/S007, Vioxx™ (Rofecoxib, Merck)**

- 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 Analgesic, Anti-Inflammatory and Ophthalmologic Drugs**
- 8:30 Merck Research Laboratories Presentation**
- 10:00 Break**
- 10:15 FDA Presentation**  
Medical: Maria Lourdes Villalba, M.D.  
GI: Lawrence Goldkind, M.D.  
CardioRenal: Shari L. Targum, M.D.  
Statistics: Qian Li, Ph.D.  
Summary: Maria Lourdes Villalba, M.D.
- 11:15 Open Public Hearing**  
Sidney M. Wolfe, M. D., Director, Public Citizen's Health Research Group
- 11:45 Lunch**
- 1:00 Discussion and Questions:**  
Vioxx questions  
General questions
- 4:30 Summary and Review**
- 5:00 Adjourn**