

Anti-Infective Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research

Holiday Inn, 8777 Georgia Ave., Silver Spring, MD

**“safety and efficacy of 1-day and 3-day dosing regimens of
azithromycin suspension (New Drug Application 50-710, Pfizer Inc.)
for the treatment of otitis media.”**

Agenda - November 7, 2001

- 8:00 Call to Order, Introductions -** L. Barth Reller, M.D., Chair
- Meeting Statement -** Thomas H. Perez, M.P.H., Executive Secretary
- 8:10 Wellcome and Introduction -** Janice Soreth, M.D., Acting Director,
Division of Anti-Infective Drug Products
- 8:30 AOM Trial Design –** Colin Marchant, M.D.,
- 9:00 Pfizer Inc. Presentation:**
Azithromycin in the Treatment of Acute Otitis Media - Michael W. Dunne, M.D., Vice
President, Clinical Development, Infectious Diseases, Pfizer Global Research and Development
- The Bacterial Pathogenesis of Acute Otitis Media** - Edward J. O'Rourke, M.D., Director,
Harvard Medical International,
- 10:45 Break**
- 11:00 FDA Presentation:**
Azithromycin for AOM – Nasim Moledina, M.D., Division of Anti-Infective Drug Products
- 11:45 Lunch**
- 12:45 Open Public Hearing**
- 1:45 Charge to the Committee, Introduction to Questions:**
- 3:00 Break**
- 3:15 Clinical Trials of AOM –** John Alexander, M.D., Division of Anti-Infective Drug Products
- 3:45 Discussion and Questions**
- 5:00 Adjourn**

Consultants and Guests

Celia Maxwell, M.D., Associate Professor of Medicine, Howard University

Jane L. Burns, M.D., Associate Professor of Pediatrics, University of Washington

Jan Patterson, M.D., Professor of Medicine and Pathology, University of Texas Health Science Center,

Colin Marchant, M.D., Boston Medical Center

Mary Glode, M.D., Professor of Pediatrics, University of Colorado Health Sciences Center

Richard Gorman, M.D., Pediatrics Subcommittee of the AntiInfective Drugs Advisory Committee

Open Public Hearing Participants

Presentations:

Michael R. Jacobs, M.D., Professor of Pathology Case Western Reserve University

Ron Dagan, M.D., Director, Pediatric Infectious Disease Unit, Soroka Medical Center

Statements for the Record: