

## **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 Welcome and Introduction** - Janice Soreth, M.D., Acting Director,  
Division of Anti-Infective Drug Products
- 8:30 Design of Clinical Trials of Antibiotic Therapy for AOM** – 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., Professor of  
Pediatrics, Harvard Medical School
- 10:30 Break**
- 10:45 FDA Presentation:**
- Azithromycin for AOM** – Nasim Moledina, M.D., Division of Anti-Infective Drug Products
- 11:15 Open Public Hearing**
- 12:15 Lunch**
- 1:15 Discussion of Questions and Vote**
- 3:00 Continuation of AOM Clinical Trials Discussion**  
**Introduction** – John Alexander, M.D., Division of Anti-Infective Drug Products

## **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**

Michael R. Jacobs, M.D., Professor of Pathology Case Western Reserve University  
Ron Dagan, M.D., Director, Pediatric Infectious Disease Unit, Soroka Medical Center  
Sidney Wolfe, M.D., Director, Public Citizen's Health Research Group