

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE (AIDAC) MEETING

AGENDA
July 11, 2002

Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD

Topic: Clinical trial design for studies of otitis media

8:30 a.m.	Call to Order	L. Barth Reller, M.D. Chair, AIDAC
	Introduction of Committee	
	Conflict of Interest Statement	Tara P. Turner, Pharm.D. Executive Secretary, AIDAC
8:40 a.m.	Guidance Development	John H. Powers, M.D. Lead Medical Officer for Antimicrobial Drug Development Office of Drug Evaluation IV FDA
8:50 a.m.	Development of Antibiotics for Otitis Media: Past, Present and Future	Janice M. Soreth, M.D. Director Division of Anti-Infective Drug Products, FDA
9:10 a.m.	Design Issues in Antimicrobial Treatment Trials of AOM	G. Scott Giebink, M.D. Professor Department of Pediatrics University of Minnesota
9:30 a.m.	Experience with Tympanocentesis/ Clinical Diagnosis of AOM	Michael Pichichero, M.D. Professor of Microbiology, Immunology, Pediatrics and Medicine University of Rochester
9:55 a.m.	Double Tympanocentesis Studies	Ron Dagan, M.D. Director Pediatric Infectious Diseases Unit Soroka Medical Center
10:25 a.m.	Limitations of Clinical-only Studies	Colin Marchant, M.D. Adjunct Associate Professor Boston University School of Medicine
10:50 a.m.	Break	

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| 11:05 a.m. | Study Designs for Acute Otitis Media Trials:
What can each design tell us? | C. George Rochester, Ph.D.
Statistician
Division of Biometrics III
FDA |
| 11:25 a.m. | Lesson Learned from Past Approvals | Thomas Smith, M.D.
Medical Officer
Division of Anti-Infective
Drug Products, FDA |
| 11:45 a.m. | Study Considerations:
Recurrent / Treatment Failure AOM | Rosemary Johann-Liang, M.D.
Medical Officer
Division of Special Pathogen and
Immunologic Drug Products
FDA |
| 12:05 p.m. | Lunch | |
| 1:05 p.m. | Open Public Hearing | |
| | | Michael R. Jacobs, M.D., Ph.D.
Case Western Reserve University
University Hospitals of Cleveland
Cleveland, Ohio |
| 2:05 p.m. | Summary and Charge to Committee | Renata Albrecht, M.D.
Acting Director
Division of Special Pathogen
and Immunologic Drug
Products, FDA |
| 2:15 p.m. | Committee Discussion | |
| 2:30 p.m. | Break | |
| 2:45 p.m. | Committee Discussion and Vote | |
| 4:00 p.m. | Adjourn | |