

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

AGENDA
January 8, 2003

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

NDA 21-144, Ketek™ (telithromycin), Aventis Pharmaceuticals, Inc., proposed for treatment of community-acquired pneumonia, acute exacerbation of chronic bronchitis, and acute maxillary sinusitis

8:00 a.m.	Call to Order	James E. Leggett, Jr., M.D. Acting Chair, AIDAC
	Introduction of Committee	
	Conflict of Interest Statement	Tara P. Turner, Pharm.D. Executive Secretary, AIDAC
8:05 a.m.	Historical Background of Ketek™ NDA	Janice Soreth, M.D. Director Division of Anti-Infective Drug Products Food and Drug Administration
8:20 a.m.	Clinical Significance of Macrolide Resistance	John H. Powers, M.D. Lead Medical Officer for Antimicrobial Drug Development Office of Drug Evaluation IV Food and Drug Administration
8:50 a.m.	Sponsor Presentation	Aventis Pharmaceuticals, Inc.
	Introduction	Steve Caffé, M.D. Head, U.S. Regulatory Affairs
	Medical Need	Paul Ianinni, M.D. Clinical Professor of Medicine Yale University School of Medicine
	Microbiology	Stephen Jenkins, Ph.D. Director of Clinical Microbiology Carolinas Medical Center
	Clinical Efficacy	Bruno Leroy, M.D. Senior Director, Clinical Development Anti-Infectives
	Human Pharmacology	Vijay Bhargava, Ph.D. Senior Director, Drug Metabolism and Pharmacokinetics

	Clinical Safety	Paul Lagarenne, M.D. Vice-President, Clinical Safety Analysis Global Pharmacovigilance
	Conclusions	Paul Ianinni, M.D.
10:35 a.m.	Break	
10:50 a.m.	FDA Presentation	
	Efficacy of Telithromycin	John Alexander, M.D., M.P.H. Medical Team Leader Division of Anti-Infective Drug Products
	Safety Summary – Phase 3	Charles Cooper, M.D. Medical Officer Division of Anti-Infective Drug Products
	Study 3014 - Safety	C. George Rochester, Ph.D. Statistician Division of Biometrics III
	Hepatic Pathology Discussion	David Kleiner, M.D., Ph.D. Laboratory of Pathology National Cancer Institute National Institutes of Health
	Post-Marketing Information	Charles Cooper, M.D.
12:30 p.m.	Lunch	
1:30 p.m.	Open Public Hearing	
2:00 p.m.	Committee Discussion and Vote	
5:00 p.m.	Adjourn	