

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
8:10 a.m.	Historical Background on Ketek™ Submission	Janice Soreth, M.D. Director Division of Anti-Infective Drug Products FDA
8:30 a.m.	Macrolide Resistance	Joshua P. Metlay, M.D., Ph.D. University of Pennsylvania Center for Clinical Epidemiology and Biostatistics
9:00 a.m.	Sponsor Presentation	Aventis Pharmaceuticals, Inc.
10:30 a.m.	Break	
10:45 a.m.	FDA Presentation	John Alexander, M.D., M.P.H. Medical Team Leader Division of Anti-Infective Drug Products
		Chuck Cooper, M.D. Medical Officer Division of Anti-Infective Drug Products
		C. George Rochester, Ph.D. Statistician Division of Biometrics III
		David Kleiner, M.D., Ph.D. Laboratory of Pathology National Cancer Institute National Institutes of Health
		Chuck 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