Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

Anti-Infective Drugs Advisory Committee in Joint Session with the
Drug Safety and Risk Management Advisory Committee
Hilton, Silver spring, Maryland

December 14-15, 2006

AGENDA

The committee will discuss the overall benefit to risk considerations for the approved product KETEK (telithromycin), new drug application (NDA) 21-144, with the current indications of: acute bacterial exacerbations of chronic bronchitis, acute bacterial sinusitis, and community acquired pneumonia, manufactured by Sanofi-Aventis.

Day 1 December 14, 2006

8:00	Call to Order and Introductions	John Edwards, M.D. Acting Chair, Anti-Infective Drugs Advisory Committee (AIDAC)
	Conflict of Interest Statement	Lt. Sohail Mosaddegh, RPh., Pharm.D., Executive Secretary, AIDAC
8:15	Welcome & Introductory Comments /Purpose of the Meeting	Gerald Dal Pan, M.D., M.H.S. Director, Office of Surveillance and Epidemiology CDER, FDA Edward Cox, M.D., M.P.H. Acting Director, Office of Antimicrobial Products CDER, FDA
8:40	**FDA Presentation**	
	Respiratory Tract Infections: Epidemiology/ Treatment	John Bartlett, M.D. Professor of Medicine Johns Hopkins School of Medicine
9:10	**Sponsor Presentation**	
	Introductory remarks	Mark Moyer, MS Deputy Head, and VP, RD
	Medical need and resistance	Don E. Low, M.D., FRCPC Professor, Department of Laboratory Medicine and Pathobiology and Department of Medicine University of Toronto, Ontario, Canada
	Overview of approval activities	Helen Edelberg, M.D., M.P.H. Associate Therapeutic Area Head, Anti-Infectives, RD

9:55	**FDA Presentation**	
	DAIOP Presentation of Ketek Data & Review	
	Regulatory History	Janice Soreth, M.D. Director Division of Anti-Infective and Ophthalmology Products, FDA
	Pre-Approval Efficacy and Safety Data	John Alexander, M.D. Clinical Team Leader Division of Anti-Infective and Ophthalmology Products, FDA
10:40	Committee Questions	
10:55	Break	
11:10	**Sponsor Presentation**	
	Post approval	
	Microbiologic surveillance	Stephen G. Jenkins, Ph.D. Clinical Professor of Pathology and Director Clinical Microbiology Laboratories, Mount Sinai school of Medicine, New York, NY
	Clinical Importance of Ery-resistant S. *pneumoniae*	John R. Lonks, M.D, Associate Professor of Medicine Brown University Medical School
	Clinical safety	Barbara Rullo, M.D. Therapeutic Area Head, GPE (Marketed Products)
11:40	**FDA Presentation**	
	5 years post-marketing ex US	Örjan Mortimer, M.D., MPA Clinical Assessor, Senior Expert Pharmacovigilance Unit, Medical Products European Medicines Agency (EMEA) Uppsala, Sweden
12:10	Committee Questions	
12:30	Lunch	
1:30	Data-Mining Evaluation of AERS/ Multiple Antibiotics	Jonathan G. Levine, Ph.D. Mathematical Statistician Office of Critical Path Programs Office of the Commissioner, FDA

2:00 **Sponsor Presentation**

Adverse events of Special interest: Hepatic

Safety overview	Barbara Rullo, M.D. Therapeutic Area Head, GPE (Marketed Products)
Expert review	James H. Lewis, M.D., FACP, FACG Professor of Medicine and Director of Hepatology Georgetown University Medical Center Washington, D.C.
Epidemiologic investigations – PHARMetrics	Wanju Dai, M.D., Dr.PH. Head, Epidemiology, Global Pharmacovigilance & Epidemiology (GPE)
Epidemiological investigation - Ingenix	Alexander M. Walker, Dr.PH. Senior VP Epidemiology, i3 Drug Safety, Adjunct Professor of Epidemiology, Department of Epidemiology Harvard School of Public Health, Boston, MA
Expert review of epidemiology	Judith Jones, M.D. Ph.D., President, CEO The Degge Group, Arlington, VA Adjunct Professor of Pharmacology Georgetown School of Medicine Washington, D.C.

3:15 **Break**

FDA Presentation

3:30	OSE Analyses of Hepatic Adverse Events	Allen Brinker, M.D., M.S. Epidemiology Team Leader Office of Surveillance and Epidemiology CDER, FDA
4:00	Hepatotoxicity	
	Assessment of Causality in Drug-Induced Hepatotoxicity	Leonard Seeff, M.D. Senior Investigator, Division of Digestive Diseases and Nutrition National Institutes of Diabetes and Digestive and Kidney Diseases, NIH
	Review of Clinical Cases and Perspective	William Lee, M.D. Director, Clinical Center for Liver Diseases University of Texas Southwestern Medical School
4:45	Committee Questions & Discussion	
5:45	**Adjourn**	

AGENDA (Day 2)

Day 2 December 15, 2006

(AIDAC)

	Conflict of Interest Statement	Lt. Sohail Mosaddegh, R.Ph., Pharm.D., Executive Secretary, AIDAC
8:15	**Sponsor Presentation**	
	Adverse events of special interest: Exacerbations of Myasthenia Gravis, syncope/loss of consciousness	
	Overview of Safety experience	Barbara Rullo, M.D. Therapeutic Area Head, GPE (Marketed Products)
	Expert review: visual	Randy Kardon, M.D. Associate Professor, Department of Ophthalmology and Visual Science, Neuro-ophthalmology Division University of Iowa Hospital and Clinics Iowa City, IA
	Expert review myasthenia gravis	Donald Sanders, M.D. Co-Director EMG Laboratory, Duke University Durham, NC
9:00	**FDA Presentation**	
	Visual AE, Loss of Consciousness and Myasthenia Gravis Analyses of AERS Reports	Ronald Wassel, Pharm.D. Safety Evaluator Office of Surveillance and Epidemiology CDER, FDA
9:45	Committee Questions	
10:15	**Break**	
10:30	**Sponsor Presentation**	
	Treatment options for respiratory tract infections, role Of Telithromycin	
	Overview and CAP	Daniel Musher, M.D. Professor of Molecular Virology & Microbiology Baylor College of Medicine, Chief of Infectious Diseases Veterans Affairs Hospital, Houston, TX
	AECB-Etiology, Outcomes and Antibiotics	Sunjay Sethi, M.D. Associate Pprofessor Department of medicine, University of Buffalo State university of New York at Buffalo, NY
	Anti-Bacterials in ABS	Berrylin J. Ferguson, M.D. Associate Professor Department of Otolaryngology, University of Pittsburg Medical Center, Pittsburg, PA

AGENDA (Day 2)
Continued

	Summary and Conclusions	Bruno Leroy, M.D. Head, Internal Medicine Franchise, Global Medical Affairs
11:00	**FDA Presentation**	

Deputy Director
Division of Drug Risk Evaluation (OSE)
CDER, FDA

11:30 Open Public Hearing

12:30 Lunch

1:30 Summary Comments & Charge to the Committee

Edward Cox, M.D., M.P.H.
Acting Director, Office of Antimicrobial Products
CDER, FDA

Gerald Dal Pan, M.D., M.H.S.
Director, Office of Surveillance and Epidemiology
CDER, FDA

2:00 Committee Discussion of Overall Risk/ Benefit & Questions

3:30 Break

5:00 Adjourn