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

AGENDA
March 4, 2003

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

NDA 21-158, Factive® (gemifloxacin) Tablets, Parexel International, U.S. Agent for LG LifeSciences, Ltd., proposed for the treatment of community-acquired pneumonia and acute bacterial exacerbation of chronic bronchitis

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.	**Opening Remarks**	Renata Albrecht, M.D. Director Division of Special Pathogen and Immunologic Drug Products, FDA
8:20 a.m.	**Adverse Cutaneous Drug Reactions**	Michael Bigby, M.D. Assistant Professor of Dermatology Harvard Medical School
8:50 a.m.	**Antimicrobial Resistance in *Streptococcus pneumoniae***	John H. Powers, M.D. Lead Medical Officer for Antimicrobial Drug Development Office of Drug Evaluation IV, FDA
9:20 a.m.	Break	
9:30 a.m.	**Sponsor Presentation**	Parexel International, US Agent for LG Life Sciences Ltd.
	Introduction	Gary Patou, M.D. President, GeneSoft Pharmaceuticals
	Unmet Medical Need	Donald E. Low, M.D. Professor, Microbiology and Medicine University of Toronto
	Efficacy	Lionel A. Mandell, M.D. Professor of Medicine Chief of Infectious Diseases McMaster University

	Safety	Gary Patou, M.D. Neil H. Shear, M.D. Professor and Chief of Dermatology University of Toronto
	Benefit/Risk and Risk Management	Gary Patou, M.D.
11:00 a.m.	Questions and Answers	
11:10 a.m.	Break	
11:20 a.m.	**FDA Presentation**	
	Microbiology	Peter Dionne Microbiologist Division of Special Pathogen and Immunologic Drug Products, FDA
	Community-Acquired Pneumonia	Regina Alivisatos, MD. Medical Officer Division of Special Pathogen and Immunologic Drug Products, FDA
	Acute Bacterial Exacerbation of Chronic Bronchitis	Eileen Navarro, M.D. Medical Officer Division of Special Pathogen and Immunologic Drug Products, FDA
	Safety	Maureen Tierney, M.D., M.Sc. Medical Officer Division of Special Pathogen and Immunologic Drug Products, FDA
12:30 p.m.	Questions and Answers	
12:40 p.m.	Lunch	
1:40 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	Mark Goldberger, M.D., M.P.H. Director Office of Drug Evaluation IV, FDA
2:10 p.m.	Committee Discussion	
3:20 p.m.	Break	
3:30 p.m.	Continued Discussion and Vote	
5:00 p.m.	Adjourn	