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

Anti-Infective Drugs Advisory Committee
Hilton Washington DC North/Gaithersburg
Gaithersburg Maryland

September 12, 2006

AGENDA

The committee will discuss the Factive (gemifloxacin mesylate) Supplemental New Drug Application 21-158/S-006, submitted by Oscient Pharmaceuticals Corporation for the proposed 5-day treatment of acute bacterial sinusitis.

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	Opening Remarks Introduction and background to Factive	Renata Albrecht, M.D. Director Division of Special Pathogen and Transplant Products (DSPTP), FDA
8:30	**<u>Sponsor Presentation</u>**	
	Introduction	Gary Patou, M.D. Director, Oscient Pharmaceuticals Corporation
	Appropriate Use of Antibiotics in ABS: A Strategy to Minimize Resistance in *streptococcus pneumoniae*	Donald E. Low, M.D. Professor, Microbiology and Medicine University of Toronto
	Gemifloxacin Efficacy Review	Berrylin J. Ferguson, M.D. Director, Division of Sino Nasal Disorders and Allergy, University of Pittsburgh
	Gemifloxacin Cutaneous Manifestations	Neil Shear, M.D. Professor and Chief of Dermatology, Director, Drug Safety Research University of Toronto
	Gemifloxacin Safety Review	Paul Waymack, M.D., Sc.D. President, Waymack Inc.
	Benefit/Risk & Conclusion	Gary Patou, M.D. Director, Oscient Pharmaceuticals

AGENDA
Continued

9:45 Questions from Committee to Sponsor

10:15 Break

10:30 **FDA Presentation**

Review of drug development for acute bacterial sinusitis	John Powers, M.D. Medical Officer Team Leader Office of Antimicrobial Products(OAP), FDA
Medical Officer Review of premarketing safety and efficacy of Factive (gemifloxacin) for acute bacterial sinusitis	Maureen Tierney, M.D. Medical Officer, DSPTP, FDA
Review of post marketing safety of Factive (gemifloxacin)	Andrew Mosholder, M.D., M.P.H. Medical Officer Division of Drug Risk Evaluation Office of Surveillance and Epidemiology, FDA

11:45 Questions from Committee to FDA

12:15 **Lunch**

1:15 Open Public Hearing

1:45 Questions and Committee Deliberation

5:00 **Adjourn**