Food and Drug Administration

Center for Drug Evaluation and Research (CDER)

Anti-Infective Drugs Advisory Committee

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 and Review of quinolone drug development/ post marketing safety	Renata Albrecht, M.D. Director Division of Special Pathogen and Transplant Products (DSPTP), FDA
8:30	**Applicant Presentation**	Oscient Pharmaceuticals Corporation
9:45	Questions from Committee to Applicant	
10:15	Break	
10:30	**FDA Presentation**	
	Introduction	
	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 Presentation of Questions and Committee Deliberation

5:00 Adjourn

Questions:

Supplemental NDA 21-158/S-006 Factive® (gemifloxacin mesylate) Tablets, Oscient Pharmaceuticals Corporation, proposed for the 5-day treatment of acute bacterial sinusitis.

1. Do the safety and effectiveness data presented demonstrate an acceptable risk/benefit profile of Factive® (gemifloxacin mesylate) for the 5-day treatment of patients with acute bacterial sinusitis?

   If yes, is there specific information regarding safety and/or efficacy that should be included in product labeling? Do you have any risk-management recommendations that should be considered for the 5-day treatment of acute bacterial sinusitis?

   If no, are there other studies or additional information that could support either safety and/or effectiveness for the 5-day treatment of acute bacterial sinusitis?