Food and Drug Administration
Center for Drug Evaluation and Research

5630 Fishers Lane, Room 1066, Rockville, Maryland 20857

Summary Minutes of the Anti-Infective Drugs Advisory Committee September 12, 2006:

The committee discussed 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.

These summary minutes for the September 12, 2006 meeting of the Anti-Infective Drugs Advisory Committee were approved on September 22, 2006.

I certify that I attended the September 12, 2006 meeting of the Anti-Infective Drugs Advisory Committee and that these minutes accurately reflect what transpired.

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LT Sohail Mosaddegh, Pharm.D., RPh.	John Edwards, M.D.
Designated Federal Officer AIDAC	Acting Chair, AIDAC

All external requests for the meeting transcripts should be submitted to the CDER, Freedom of Information Office.

The following is an internal report which has not been reviewed. A verbatim transcript will be available in about 2 weeks, sent to the Office of Anti-Microbial Products and posted on the FDA website at http://www.fda.gov/ohrms/dockets/ac/cder06.html#AntiInfective

Prior to the meeting, the members and the invited consultants had been provided the background material from the FDA and from the Sponsor. The meeting was called to order by John Edwards, M.D. (Committee Chair); the conflict of interest statement was read into the record by LT Sohail Mosaddegh, Pharm.D., R.Ph. (Designated Federal Officer). There were approximately 150 persons in attendance. There were 2 speakers for the Open Public Hearing sessions.

Attendance:
Anti-Infective Drugs Advisory Committee Members:
John S Bradley, M.D., John E. Edwards Jr. , M.D., Kathleen M. Gutierrez, M.D., Joan Hilton, Sc.D., Carol Kauffman, M.D., Donald M. Poretz, M.D., Gregory Townsend, M.D., Allan Tunkel, M.D., Ph.D., Bernard Wiedermann M.D., Annie Wong-Beringer, Pharm.D.

Anti-Infective Drugs Advisory Committee consultants (voting):
Richard Frothingham, M.D., F.A.C.P.

Dermatologic and Ophthalmic Drugs Advisory Committee consultants (voting):
Michael Bigby, M.D.

Drug Safety and Risk Management Advisory Committee (Voting):
Jacqueline S. Gardner, Ph.D., M.P.H., Peter A. Gross, M.D.

FDA Participants:
Renata Albrecht, M.D., Edward E. Cox, M.D., M.P.H., Andrew Mosholder, M.D., M.P.H., Robert T. O'Neill, Ph.D., John Powers, M.D., Leonard Sacks, M.D., Robert Temple, M.D., Maureen Tierney, M.D.,

Open Public Hearing Speakers:

Mark P. Cohen, Kristen Suthers

Issue: The committee discussed 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.

The agenda was as follows:

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
Opening Remarks Introduction and background to Factive	Renata Albrecht, M.D. Director Division of Special Pathogen and Transplant Products (DSPTP), FDA

Sponsor Presentation

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 Manifistations	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

Questions from Committee to Sponsor

Break

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

Questions from Committee to FDA

Lunch

Open Public Hearing

Questions and Committee Deliberation

Adjourn

Questions to the Committee:

1. Regardless of safety considerations has efficacy been demonstrated in the use of Factive® (gemifloxacin mesylate) for the 5-day treatment of patients with acute bacterial sinusitis?

   YES: 4 **NO: 10**

2. 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?

   YES: 2 **NO: 11** **Absentee: 1**

   a. 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?

   (See transcripts for detailed discussion)

   B 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?

   (See transcripts for detailed discussion)