



NDA 21-158/S-007

Oscient Pharmaceuticals Corporation  
Attention: John Driscoll, RAC  
Manager, Regulatory Affairs  
1000 Winter Street, Suite 2200  
Waltham, MA 02451

Dear Mr. Driscoll:

Please refer to your supplemental new drug application dated November 18, 2005, received November 21, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Factive<sup>®</sup> (gemifloxacin mesylate) Tablets, 320 mg.

We acknowledge receipt of your submissions dated September 18, September 19, September 28, and October 31, 2006, and February 20, April 13, and April 19, 2007.

Your submission of October 31, 2006 constituted a complete response to our September 21, 2006 action letter.

This supplemental new drug application provides for the use of Factive<sup>®</sup> (gemifloxacin mesylate) Tablets, 320 mg for the 5-day treatment of selected susceptible strains of *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae* for community-acquired pneumonia.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA 21-158/S-007."

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Brenda Marques, Pharm.D., Regulatory Project Manager, at (301) 796-1600.

Sincerely,

*{See appended electronic signature page}*

Renata Albrecht, M.D.  
Director  
Division of Special Pathogen and  
Transplant Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

Enclosure (PI and PPI)

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/s/

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Renata Albrecht  
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