



NDA 21-158/S-005

Oscient Pharmaceuticals Corporation
Attention: Mr. Thomas Class, RAC
Director, Regulatory Affairs
1000 Winter Street
Suite 2200
Waltham, MA 02451

Dear Mr. Class:

Please refer to your supplemental new drug application dated August 12, 2005, received August 15, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Factive[®] (gemifloxacin mesylate) Tablets, 320 mg.

We acknowledge receipt of your submissions dated February 16 and April 25, 2006. Your submission dated April 25, 2006, constituted a complete response to our approvable letter dated February 15, 2006.

This “Changes Being Effected” (CBE) supplemental new drug application provides for the following changes to the approved package insert (PI) and patient package insert (PPI) (additions are noted in double underline and deletions are in ~~strike through~~):

Package insert (PI)

1. PRECAUTIONS/ Information for Patients

Patients should be counseled: ...that increases of the International Normalized Ratio (INR), or prothrombin time (PT), and/or clinical episodes of bleeding have been noted with concurrent administration of warfarin or its derivatives, and FACTIVE ~~gemifloxacin~~. Patients should notify their physicians if they are taking warfarin or its derivatives.

2. PRECAUTIONS/ Drug Interactions

FACTIVE had no significant effect on the anticoagulant effect of warfarin in healthy subjects on stable warfarin therapy. However, post-marketing reports of increases in the INR, and/or PT, and/or clinical episodes of bleeding in patients have been noted with the use of quinolones, including FACTIVE ~~gemifloxacin~~, and warfarin, or its derivatives. In addition, infectious disease and its accompanying inflammatory process, age and general status of the patient are risk factors for increased anticoagulation activity. Therefore, the PT, INR, or other suitable coagulation test should be closely monitored if a quinolone antimicrobial, including FACTIVE, is administered concomitantly with warfarin or its derivatives.

Patient Package Insert (PPI)

1. **Drug Interactions**

What about other medicines I am taking?

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins, and dietary supplements. FACTIVE and other medicines may affect each other, causing serious side effects. **Be sure to tell your healthcare provider if you take:...**

- medicines to thin your blood (called oral anticoagulants) such as Coumadin® or warfarin.

In addition, this CBE supplemental new drug application provides for several minor editorial revisions to the approved package insert (PI) and patient package insert (PPI) not listed in this letter.

We have completed the 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 (enclosed).

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert and text for the patient package insert. These revisions are the terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-158/S-005.**" Approval of this submission by FDA is not required before the labeling is used.

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: package insert and
patient package insert

**This is a representation of an electronic record that was signed electronically and
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/s/

Renata Albrecht
10/26/2006 11:32:32 AM