



NDA 21-158/S-021

## SUPPLEMENT APPROVAL

Cornerstone Therapeutics, Inc.  
Attention: Ashlie Adams, M.S.  
Manager, Regulatory Affairs  
1255 Crescent Green Drive, Suite 250  
Cary, NC 27518

Dear Ms. Adams:

Please refer to your Supplemental New Drug Application (sNDA), dated August 18, 2011, received August 19, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Factive (gemifloxacin mesylate) Tablet.

We acknowledge receipt of your amendment dated September 6, 2011.

This "Prior Approval" supplemental new drug application provides for the:

1. Addition of 'pseudotumor cerebri' to the **WARNINGS, Central Nervous System Effects/ Disorders** subsection as follows:

"Although not seen in Factive clinical trials, convulsions, increased intracranial pressure (including pseudotumor cerebri), and toxic psychosis have been reported in patients receiving other fluoroquinolones."

2. Removal of *Enterococcus faecalis* ATCC 29212, MIC range ( $\mu\text{g/mL}$ ) 0.016-0.12, from the quality control parameters section of the package insert.

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

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide), with the addition of any labeling changes in pending

“Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **REPORTING REQUIREMENTS**

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 Fariba Izadi, Pharm.D., Regulatory Project Manager, at (301) 796-0563.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, MD, MPH  
Deputy Director for Safety  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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SUMATHI NAMBIAR  
10/18/2011