



NDA 21814/S-014  
NDA 22292/S-07

**SUPPLEMENT APPROVAL**

Boehringer Ingelheim Pharmaceuticals, Inc.  
Attention: Robert O. Kumi, PhD  
Associate Director-Drug Regulatory Affairs  
900 Ridgebury Rd  
P.O. Box 368  
Ridgefield, CT 06877-0368

Dear Dr. Kumi:

Please refer to your Supplemental New Drug Applications (sNDA) for NDA 22292 and NDA 21814 dated November 25, 2013 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for APTIVUS<sup>®</sup> (tipranavir) capsules, 250 mg, and APTIVUS<sup>®</sup> (tipranavir) oral solution, 100 mg/mL, respectively.

We acknowledge receipt of your amendments on the following dates.

December 12, 2013	February 14, 2014
December 19, 2013	February 28, 2014

These Prior Approval supplemental new drug applications propose to update the labeling's CONTRAINDICATIONS section with information on pimozone, and DRUG INTERACTIONS, Table 4 with information on etravirine, rilpivirine, boceprevir, telaprevir, quetiapine, and colchicine.

We have completed our review of these supplemental applications as amended. They are 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 that includes labeling changes for these NDAs, 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 Nina Mani, Regulatory Project Manager, at (240) 402-0333 or the Division’s main number at (301) 796-1500.

Sincerely,

*{See appended electronic signature page}*

Kendall A. Marcus, MD  
Deputy Director of Safety  
Division of Antiviral 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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KENDALL A MARCUS  
04/07/2014