



NDA 21-814 SLR-006

NDA 22-292 SLR-001

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Charles R. Mazzarella
Senior Associate Director, Drug Regulatory Affairs
900 Ridgebury Rd
P.O. Box 36
Ridgefield, CT 06877-0368

Dear Mr. Mazzarella:

Please refer to your supplemental new drug applications dated December 18, 2008, received December 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aptivus® (tipranavir), 250 mg capsules and Aptivus® (tipranavir) 100 mg/mL oral solution.

We acknowledge receipt of your submissions dated April 21, 2009, and June 2, 2009.

These supplemental new drug applications provide the following revisions to the package insert (PI):

- update of the Drug Interactions and Clinical Pharmacology sections based on the results of drug interaction studies 1182.105, 1182.85 and a retrospective analysis of enfuvirtide interaction data from the RESIST trials.
- add the results of thorough QTc study 1182.60 to Section 12.2, Pharmacodynamics

We have completed our review of these applications as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Approval of these supplements fulfills the following postmarketing commitment acknowledged in our June 22, 2005, approval letter:

18. Conduct a formal QT prolongation study

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl/html> that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. **For administrative purposes, please designate these submissions “SPL for approved NDA 21-814/S-006 and NDA 22-292/S001.”**

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The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted on INSERT DATE).

LETTERS TO HEALTH CARE PROFESSIONALS

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Sherly Abraham, R.Ph., Regulatory Project Manager, at (301)796-3198.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package Insert
Patient Package Insert

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Kendall Marcus
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