



NDA 21-976/S-010

Tibotec, Incorporated  
Attention: Susan Fiordeliso  
Manager, Global Regulatory Affairs  
1020 Stony Hill Road, Suite 300  
Yardley, PA 19067

Dear Ms. Fiordeliso:

Please refer to your supplemental new drug application dated and received December 15, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PREZISTA® (darunavir) Tablets.

We acknowledge receipt of your submissions dated January 9, 2009, January 30, 2009, April 3, 2009, April 14, 2009, and April 23, 2009.

This supplemental new drug application provides for revisions to the DRUG INTERACTIONS and CLINICAL PHARMACOLOGY sections of the package insert to include results from a drug-drug interaction study between darunavir/ritonavir twice daily and buprenorphine/naloxone. In addition, the results of this drug-drug interaction study were added to the "CAN PREZISTA BE TAKEN WITH OTHER MEDICATIONS?" section of the patient package insert.

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.

Approval of this supplement fulfills the following postmarketing commitment number acknowledged in our June 23, 2006, approval letter:

6. Conduct an *in vivo* drug interaction study between darunavir/rtv bid and buprenorphine/naloxone.

### **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 and patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. **For administrative purposes, please designate this submission "SPL for approved NDA 21-976/S-010."**

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert).

In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

**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 Stacy Powers Newalu, M.P.H., Regulatory Project Manager, at (301) 796-3978.

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)

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/s/

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Kendall Marcus  
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