



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-976/S-011

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 February 27, 2009, received February 27, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PREZISTA® (darunavir) tablets.

This "Changes Being Effected" supplemental new drug application provides for revision to the U.S. Package Insert and Patient Package Insert to include 150 mg tablets.

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.

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

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.

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 questions, call Stacy 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, and immediate container label

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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 Marcus  
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