DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-976/S-001

Tibotec, Inc.
Attention: Jenny Z. Lin, PharmD
Manager, Global Regulatory Affairs
1020 Stony Hill Road, Suite 300
Yardley, PA 19067

Dear Dr. Lin:

Please refer to your supplemental new drug application dated October 31, 2006, received November 1, 2006, 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 a revision to the INDICATIONS AND USAGE, Description of Clinical Studies, Treatment-Experienced Subjects, Studies TMC114-C213 and TMC114-C202 section of the Package Insert (PI). The following sentence was changed from "Selected PI(s) in the control arm included: lopinavir/ritonavir in 36%, (fos)amprenavir in 34%, saquinavir in 35% and atazanavir in 17%; 23% of the control subjects used dual-boosted PIs" to "Selected PI(s) in the control arm included: lopinavir in 36%, (fos)amprenavir in 34%, saquinavir in 35% and atazanavir in 17%; 98% of control subjects received a ritonavir boosted PI regimen out of which 23% of control subjects used dual-boosted PIs." These changes were requested in order to furnish adequate information for the safe and effective use of the drug.

We completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 31, 2006.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Elizabeth Thompson, M.S., Regulatory Project Manager, at (301) 796-0824.

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

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

/s/

Debra Birnkrant
11/20/2006 11:01:17 AM
NDA 21-976