DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-976/S-005

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

Dear Ms. Lin:

Please refer to your supplemental new drug application (sNDA) dated October 23, 2007, received October 25, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PREZISTA (darunavir) Tablets.

We acknowledge receipt of your amendments dated December 14, 2007, and February 15, 2008.

This new drug application provides for the addition of a new 600 mg tablet strength for darunavir.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed upon draft content of labeling submitted on February 25, 2008.

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(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. 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-005**."

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your October 23, 2007 submission containing final printed carton and container labels. Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes,

21-976/S-005." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

POSTMARKETING COMMITMENTS

We remind you of your postmarketing study commitment in your submission, sent via email, dated February 25, 2008. This commitment is listed below.

1. Revise the debossment on the 600mg tablet to make it meet the requirements of a unique identifier.

Proposal Submission: March 3, 2008

Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments should be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Rebecca McKnight, Regulatory Health Project Manager, at (301) 796-1765.

Sincerely,

{See appended electronic signature page}

Eric P. Duffy, Ph.D.
Director
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure: Draft Content of Labeling

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

/s/

Eric Duffy
2/25/2008 05:12:19 PM