DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-187/S-003 **SUPPLEMENT APPROVAL**

Tibotec, Incorporated
Attention: Susan Fiordeliso
Manager, Global Regulatory Affairs
1125 Trenton-Harbourton Rd.
Titusville, NJ 08560

Dear Ms. Fiordeliso:

Please refer to your supplemental new drug application dated and received August 7, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for INTELENCE™ (etravirine) 100 mg tablets.

We acknowledge receipt of your submissions dated December 8, 2009, January 22, 2010 and February 19, 2010.

This Prior Approval supplemental new drug application provides for updates to the U.S. Package Insert and Patient Package Insert with information on the drug interactions between etravirine and fluconazole, voriconazole, lopinavir/ritonavir, and clopidogrel and to include information on coadministration of protease inhibitors with or without ritonavir.

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 postmarketing commitment 8 as outlined in the January 18, 2008, approval letter and described below:

Conduct an *in vivo* drug-drug interaction study between etravirine and fluconazole.

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)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions listed in the enclosed labeling (text for the package insert, and patient package insert). These revisions are terms of the NDA approval. For administrative purposes, please designate this submission, "**SPL for approved NDA 22-187/S-003.**

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22187	SUPPL-3	TIBOTEC INC	TMC 125 ETRAVIRINE

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

/s/

KENDALL A MARCUS
02/23/2010