DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-187/S-002 **SUPPLEMENT APPROVAL**

Tibotec, Inc
Attention: Susan Fiordeliso
Sr. 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 August 18, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Intelence™.

This Changes Being Effected supplemental new drug application provides for revisions to the U.S. Package insert and the Patient Package insert to strengthen warnings for severe skin and hypersensitivity reactions as well as adding a Postmarketing Experience section.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on August 18, 2009.

CONTENT OF LABELING

Within 14 days from the date of this letter, please amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format that includes the changes approved in this supplemental application.

We note that your August 18, 2009 submission includes final printed labeling (FPL) for your package insert and patient package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

LETTERS TO HEALTH CARE PROFESSIONALS

Please submit an electronic copy of the “Dear Health Care Professional” letter, communicating important safety related information about this drug product to 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

Final Labeling Text

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22187	SUPPL-2	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
09/15/2009