DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-814/S-001
NDA 21-814/S-002

Nancy McKay
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877-0368

Dear Ms. McKay:

Please refer to your supplemental new drug applications dated December 28, 2005 and June 29, 2006, received December 29, 2005 and June 30, 2006, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aptivus® (tipranavir capsules).

The "Changes Being Effected in 30 days" supplemental new drug application dated December 28, 2005 provides for new information in the WARNINGS and PRECAUTIONS sections regarding drug interactions with fluticasone, trazadone, and PDE5 inhibitors as requested by the FDA in a letter dated October 4, 2005.

The "Changes Being Effect in 30 days" supplemental new drug application dated June 29, 2006 provides new information in the Boxed Warning, Indication and Usage, Warnings, Precaution (Information for Patients), and Adverse Reactions sections regarding the risk of fatal and nonfatal intracranial hemorrhage (ICH) and platelet aggregation inhibition findings in patients receiving Aptivus® Capsules. The Patient Package Insert has also been revised.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

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
WO 22, Room 4447
10903 NEW HAMPSHIRE AVENUE
Silver Spring, MD 20993-0002

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, please contact Tanima Sinha, M.S., Regulatory Project Manager, at (301) 796-0812.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant
Director
Division of Antiviral Products
Office of Antimicrobial Products

Enclosure: Final Approved Label

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

/s/

Jeffrey Murray
8/11/2006 03:07:40 PM