DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-814 SLR004

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Nancy L. McKay, P.E.
Senior Associate Director, Drug Regulatory Affairs
900 Ridgebury Rd
P.O. Box 368
Ridgefield, CT 06877-0368

Dear Ms. McKay:

Please refer to your supplemental new drug application dated February 28, 2007, received March 1, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aptivus® (tipranavir) capsules 250mg.

These "Changes Being Effected" supplemental new drug application provide for:

- Inclusion of information to the WARNINGS: Effect on Platelet Aggreation and Coagulation subsection and the ANIMAL PHARMACOLOGY AND TOXICOLOGY section regarding co-administration of tipranavir and vitamin E.

We completed our review of this application and agree with the proposed revision to the WARNINGS and ANIMAL PHARMACOLOGY AND TOXICOLOGY sections of the label.

This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below:

- Please note under ANIMAL PHARMACOLOGY AND TOXICOLOGY the correction made to the word *coagulation*

In preclinical studies of tipranavir in dogs, an effect on coagulation parameters was not seen. Co-administration of tipranavir and vitamin E has not been studied in dogs.

If you have any questions, call Jaewon Hong, Regulatory Project Manager, at (301) 796-2013.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Anti-Viral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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
5/14/2007 12:17:28 PM
NDA 21-814