DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-567/S-005

Bristol-Myers Squibb Pharmaceutical Research Institute
Attention: Lisa Percival
5 Reasearch Blvd
P.O. Box 5100
Wallingford, CT 06492-7660

Dear Ms Percival:

Please refer to your supplemental new drug application dated June 28, 2005, received June 28, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for atazanavir (REYATAZ) 100mg, 150mg & 200mg capsules.

We acknowledge receipt of your submission dated June 28, 2005.

This "Changes Being Effected" supplemental new drug application provides new labeling text addressing drug-drug interactions between atazanavir (with or without ritonavir) and fluticasone and trazodone.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling submitted June 28, 2005.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-567/S-005**." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Vasavi Reddy, RPh, MPH, Regulatory Project Manager, at (301) 827-2413.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Division Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation & Research
Food and Drug Administration

Enclosure (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
7/18/05 04:57:28 PM