DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-567/S-007

Bristol-Myers Squibb Company
Attention: Lisa Percival
Associate Director
5 Research Parkway
Signature Bldg.-3SIG-515
Wallingford, CT 06492

Dear Mrs. Percival:

Please refer to your supplemental new drug application dated July 27, 2005, received July 28, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Reyataz®(atazanavir sulfate) Capsules.

This supplemental new drug application provides for *in vitro* inhibition data and clinical drug-drug interaction information regarding coadministration of atazanavir and/or atazanavir/ritonavir with proton pump inhibitors, H2 receptor antagonists, methadone, rifampin, enteric-coated didanosine and tenofovir.

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 patient package insert submitted January 25, 2006.

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-007.**" Approval of this submission by FDA is not required before the labeling is used.

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 Paras M. Patel, Regulatory Project Manager, at (301) 796-0783.

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

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

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