DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-567/S-014

Bristol-Myers Squibb Company
Attention: Lisa Percival, Associate Director
5 Research Parkway
Signature 91 Bldg.-3SIG-515
Wallingford, CT 06492

Dear Mrs. Percival:

Please refer to your supplemental new drug applications dated March 30, 2007, received March 31, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Reyataz® (atazanavir) capsules.

Reference is also made to the FDA comments dated October 18, 2007, November 21, 2007, December 3, 2007 and December 18, 2007 and to your correspondence dated November 29, 2007 and December 6, 2007.

This Prior Approval Supplemental application proposes the following change:

- ***Revisions to the US package insert to provide clinical drug-drug interaction information regarding the administration of atazanavir and/or atazanavir/ritonavir with food, proton pump inhibitors, H2 receptor antagonists, acetaminophen, fluconazole, and in patients with renal impairment.***

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.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-567/ S-014**." 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, R.Ph., 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

Enclosure (Approved Labeling)

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
12/21/2007 08:53:20 AM
NDA 21-567