DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-567/S-001

Bristol-Myers Squibb
Margo Heath-Chiozzi, M.D.
Executive Director
Bristol-Myers Squibb Pharmaceutical Company
Regulatory Sciences, Dept. 718
5 Research Parkway
Signature 91 Building, 3SIG-506
Wallingford, CT 06492

Dear Dr. Heath-Chiozzi:

Please refer to your supplemental labeling review application dated September 15, 2003, received September 16, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for atazanavir (Reyataz®) 100mg, 150mg and 200mg capsules.

We acknowledge receipt of your submission(s) dated:
January 21, 2004 February 10, 2004
January 29, 2004 March 10, 2004
February 9, 2004 March 16, 2004

We completed our review of this application and have concluded that adequate information has been presented; therefore, 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 draft package insert and patient package insert submitted/emailed on March 16, 2004.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-567 /SLR-001". Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Antiviral Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, Regulatory Project Manager, at (301) 827-2413.

Sincerely,

{See appended electronic signature page}

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

Attachement:
1. draft PI
2. draft PPI

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

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