DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21567/S-026

SUPPLEMENT APPROVAL

Bristol Myers Squibb Company
Attention: Hwei-Gene Wang, Ph.D.
Associate Director, US Liaison
5 Research Parkway
Room 215U, Mailstop 2AW-708
Wallingford, CT 06492

Dear Dr. Wang:

Please refer to your Supplemental New Drug Application (sNDA) dated December 17, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Reyataz (atazanavir sulfate) 100, 150, 200 and 300 mg capsules.

We acknowledge receipt of your amendments dated: February 17, 2011, February 25, 2011, March 7, 2011, April 11, 2011, May 6, 2011 (2), June 1, 2011, June 9, 2011, July 5, 2011, August 25, 2011, September 19, 2011, October 4, 2011, and October 7, 2011.

This "Prior Approval" supplemental new drug application proposed the following revisions to the package insert:

- Revise the DOSAGE AND ADMINISTRAION, "Recommended Pediatric Dosage" subsection to revise the capsule dosing recommendation for both treatment-naïve and treatment-experienced pediatric patients based on modeling and simulation data and clinical data obtained in patients receiving the proposed doses or higher
- Revise ADVERSE REACTIONS, "Clinical Trial Experience in Pediatric Patients" section with safety data up to 96 weeks
- Revise CLINICAL PHARMACOLOGY, 12.3 PHARMACOKINETICS, "Pediatrics" subsection to include predicted PK parameters in pediatric patients based on the revised doses
- Revise CLINICAL STUDIES, 14.3 "Pediatric Patients" subsection with efficacy data up to 96 weeks

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the package insert and patient package enclosed, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to < 3 months because there is evidence suggesting that the drug product would be unsafe in this pediatric group. Atazanavir should not be administered to pediatric patients below the age of 3 months due to the risk of kernicterus.

We are deferring submission of your pediatric study for ages ≥ 3 months to < 6 years for this application because the product is ready for approval in patients ≥ 6 to < 18 years of age and atazanavir powder for oral solution is currently under study in the ≥ 3 months to < 6 year age group.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

1244-1 Deferred pediatric study or studies under PREA for the treatment of HIV - 1 infection in pediatric patients ages greater than or equal to 3 months to 18 years to obtain a minimum of 100 patients followed for safety for a minimum of 24 weeks

at the recommended dose or any higher doses studied during pediatric development.

Final Report Submission: 12/2010

Reports of this required pediatric postmarketing study must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

We note that you have fulfilled the pediatric study requirement for ages ≥ 6 years to < 18 years for this application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

REPORTING REQUIREMENTS

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 Sohail Mosaddegh, Pharm.D., regulatory project manager, at (301) 796-4876 or 301-796-1500.

Sincerely yours,

{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:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JEFFREY S MURRAY
10/17/2011