DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21567/S-031

SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company
Attention: Hwei-GeneWang, Ph.D.
Associate Director, Global Regulatory and Safety Sciences, US
5 Research Parkway, Room 285B
Mailstop 2DW-206
Wallingford, CT 06492

Dear Dr. Wang:

Please refer to your Supplemental New Drug Application (sNDA) dated July 31, 2012, received July 31, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Reyataz (atazanavir sulfate), 100 mg, 150 mg, 200 mg and 300 mg capsules.

We acknowledge receipt of your amendments dated December 27, 2012 and January 18, 2013.

This Prior Approval supplemental new drug application proposes the following changes to the package insert or patient package insert:

- To revise the WARNINGS AND PRECAUTIONS, Nephrolithiasis and Patient Information sections with information regarding cholelithiasis
- To add interstitial nephritis to ADVERSE REACTIONS, Postmarketing Experience subsection
- To update the DRUG INTERACTIONS, Established and Other Potentially Significant Drug Interactions subsection, Table 13 with information regarding coadministration with boceprevir, carbamazepine, phenytoin, phenobarbital, lamotrigine, and voriconazole
- To update CLINICAL PHARMACOLOGY, Pharmacokinetics subsection, Tables 17 and 18, with drug-drug interaction information for boceprevir and voriconazole
- To add boceprevir, phenobarbital, phenytoin and carbamazepine to the patient package insert

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.

CONTENT OF LABELING

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 enclosed labeling (text for the package insert, text for the patient package insert), 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 that includes labeling changes 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).

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
Office of Prescription Drug Promotion (OPDP)
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 Office of Prescription Drug Promotion (OPDP), 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 Abiola Olagundoye-Alawode, Pharm.D., Regulatory Project Manager, at (301) 796-3982.

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(S):
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/

KENDALL A MARCUS
01/30/2013