DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21567/S-036

SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company
Attention: Lisa Percival, Director, Global Regulatory Strategy
5 Research Parkway, Mailstop 2CW-506
Wallingford, CT 06492

Dear Ms. Percival:

Please refer to your Supplemental New Drug Application (sNDA) dated August 26, 2014, received August 26, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Reyataz® (atazanavir) Capsules.

This "Changes Being Effected" supplemental new drug application provides for revised artwork for the Reyataz Capsule packaging.

APPROVAL & LABELING

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

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your August 26, 2014, submission containing final printed carton and container labels.

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 Rebecca McKnight, Regulatory Business Process Manager, at (301) 796-1765.

Sincerely,

{See appended electronic signature page}

Thomas F. Oliver, Ph.D.
Branch Chief, Branch VI
Division of New Drug Quality Assessment II
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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

/s/

THOMAS F OLIVER
02/26/2015