NDA 021567/S-047

SUPPLEMENT APPROVAL

Bristol Myers Squibb Co
Attention: Shruti Patel
Associate Director, Global Regulatory Sciences
P.O. Box 5326
Princeton, NJ 08543-5326

Dear Ms. Patel:

Please refer to your Supplemental New Drug Application (sNDA) dated November 1, 2022, received November 1, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Reyataz (atazanavir sulfate) capsule.

We also refer to our approval letter dated April 14, 2023, which contained the following error: The provides for statement omitted 'quality control testing'

This replacement approval letter incorporates the correction of the error. The effective approval date will remain April 14, 2023, the date of the original approval letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for:

- Addition of (b) (4) an alternate site for drug product manufacturing and quality control testing for 200 mg and 300 mg REYATAZ capsules

APPROVAL

We have completed our review of this supplemental application. This supplement is approved.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Omolara Oyinlola-Adeyemi, Regulatory Business Process Manager, at (240) 402 – 3842 or Omolara.Oyinlola-Adeyemi@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

David B. Lewis, Ph.D.
Chief, Branch II
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

David Lewis

Digitally signed by David Lewis
Date: 5/09/2023 11:08:37AM
GUID: 508da72000029f287fa31e664741b577