



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-567/S-018

Bristol-Myers Squibb Company
Attention: Lisa Percival, Senior Director
5 Research Parkway
Signature 91 Bldg.-3SIG-515
Wallingford, CT 06492

Dear Mrs. Percival:

Please refer to your supplemental new drug application dated February 5, 2008, received February 6, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Reyataz® (atazanavir sulfate) Capsules.

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

Revisions to the US package insert to provide updates to the WARNINGS (Drug Interactions with rosuvasatin and Cardiac Conduction Abnormalities), ADVERSE REACTIONS (Postmarketing Experience for cardiac and gallbladder events) and PATIENT INFORMATION (Possible side effects of REYATAZ, REYATAZ with other medicines and REYATAZ disposal statement).

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Paras M. Patel, R.Ph., Regulatory Project Manager, at (301) 796-0783.

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 (Approved 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 Murray
2/20/2008 02:52:20 PM