



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-567/S-008

NDA 21-567/S-011

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

Dear Mrs. Percival:

Please refer to your supplemental new drug applications dated April 25, 2006 and July 26, 2006, received April 26, 2006 and July 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Reyataz® (atazanavir sulfate) Capsules.

These "Changes Being Effected" supplemental new drug applications provides for:

- S008- Changes to the US package insert ADVERSE REACTIONS section, which include updating post-marketing safety information.
- S011- Changes to the US package insert CLINICAL PHARMACOLOGY: Microbiology section, as requested in FDA communication dated May 19, 2006.

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).

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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
8/9/2006 12:10:23 PM