



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-567/S-012

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 February 6, 2007, received February 7, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Reyataz® (atazanavir) capsules.

Reference is also made to your submissions dated March 15, 2007.

This supplemental new drug application provides for:

- ***Revisions to the PRECAUTIONS section of the US package insert to include statements of cases of nephrolithiasis reported during post-marketing surveillance in HIV-infected patients receiving atazanavir therapy.***

We completed our review of this application, as amended. This application is 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)

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/s/

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Jeffrey Murray  
3/22/2007 04:45:12 PM