



NDA 21-567/S-022

SUPPLEMENT APPROVAL

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

Dear Ms. Percival:

Please refer to your supplemental new drug application dated July 22, 2009, received July 22, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for REYATAZ® (atazanavir sulfate) 100mg, 150 mg, 200 mg, and 300 mg capsules.

We acknowledge receipt of your submissions dated November 24, 2009, January 7, 2010, and January 21, 2010.

This Prior Approval supplemental new drug application was submitted to add the results of a drug-drug interaction study of atazanavir with ritonavir and rifabutin and the results of an interaction study from published literature regarding atazanavir with or without ritonavir and buprenorphine to the Drug Interactions and Clinical Pharmacology sections of the package insert.

In addition, rifabutin and buprenorphine were added to “The following medicines may require your healthcare provider to monitor your therapy more closely,” subsection under “What important information should I know about taking Reyataz with other medicines” of the patient package insert.

We have 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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is

identical to the package insert and patient package insert enclosed. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-567/S-022".

LABELING

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert).

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

LETTERS TO HEALTH CARE PROFESSIONALS

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Sherly Abraham, R.Ph., Regulatory Project Manager, at (301)796-3198.

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

Enclosures:
Package Insert
Patient Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21567	SUPPL-22	BRISTOL MYERS SQUIBB CO	REYATAZ (ATAZANAVIR SULFATE)

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

/s/

SHERLY ABRAHAM
01/22/2010

KENDALL A MARCUS
01/22/2010