



NDA 21-567/S-017

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

Dear Ms. Percival:

Please refer to your supplemental new drug application dated December 21, 2007, received December 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for REYATAZ® (atazanavir sulfate) capsules.

We acknowledge receipt of your submissions dated:

December 21, 2007	April 18, 2008	June 13, 2008	July 2, 2008
July 15, 2008	August 8, 2008	August 28, 2008	September 4, 2008

This supplemental new drug application provides for an alternative dosing regimen of REYATAZ® (atazanavir sulfate) co-administered with ritonavir for the treatment of HIV-1 infection in treatment-naïve patients.

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.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions "**SPL for approved supplement NDA 21-567/S-017**". The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert).

Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We previously waived the pediatric study requirement for ages < 3 months because there is evidence strongly suggesting that the drug product would be unsafe in this pediatric age group.

We are deferring submission of your pediatric studies for ages \geq 3 months to 6 years for this application because this product is ready for approval for use in adults and the pediatric study(ies) have not been completed. The study or studies will determine the pharmacokinetic profile, safety and activity of atazanavir with or without-ritonavir in pediatric subjects ages \geq 3 months to 6 years.

Your deferred pediatric studies required by section 505B(a) of the Act are required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Act.

- 1. Deferred pediatric study or studies under PREA for the treatment of HIV-1 infection in pediatric patients ages \geq 3 months to 18 years to obtain a minimum of 100 patients followed for safety for a minimum of 24 weeks at the recommended dose or any higher doses studied during pediatric development.**

Final Report Submission: December 15, 2010

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment should be clearly designated "**Required Pediatric Study Commitments.**"

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Antiviral Products and two copies of both the promotional materials and the package inserts directly to:

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

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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, Regulatory Project Manager, at (301) 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: (Final Draft Label):

**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
9/30/2008 09:48:41 AM