



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-567/S-015

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 September 27, 2007, received September 26, 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: October 5, 2007, December 1, 2007, January 4, 2008, January 23, 2008, January 29, 2008, March 11, 2008, March 14, 2008, March 17, 2008, March 19, 2008, March 21, 2008 and March 24, 2008.

This supplemental new drug application provides for the use of REYATAZ® (atazanavir sulfate) capsules for the treatment of HIV-1 infection in pediatric patients (ages 6 to 18 years of age).

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 and carton label submitted March 24, 2008. 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.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred.

We previously waived the pediatric study requirement for ages < 3 months. Reference is also made to your request for a partial pediatric deferral for pediatric patients ≥ 3 months to 6 years of age. We are deferring submission of your pediatric studies for ages ≥ 3 months to 6 years to determine safe and appropriate dosing. The study or studies will determine the pharmacokinetic profile, safety and activity of atazanavir with or without-ritonavir in pediatric subjects ages ≥ 3 months to 6 years.

We are therefore changing the terms of the previously deferred study, identified in the July 6, 2004 approval letter (S-002). 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 ≥ 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.**"

You are released from the following commitment established under NDA 21-567/S-002:

1. A pediatric study or studies under PREA for the treatment of HIV infection in pediatric patients ages greater than or equal to 3 months to 18 years to determine safe and appropriate dosing.

Final Report Submission: October 31, 2006

Within 14 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. 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-015.**" In addition, amend any pending applications for Reyataz® (NDA 21-567/S-016 and NDA 21-567/S-017) with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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/

Debra Birnkrant
3/25/2008 04:37:51 PM
NDA 21-567