



NDA 21-567/S-004

Margo Heath-Chiozzi, M.D.
Executive Director
Bristol-Myers Squibb Pharmaceutical Company
Regulatory Sciences, Dept. 718
5 Research Parkway
Signature 91 Building, 3SIG-506
Wallingford, CT 06492

Dear Dr. Heath-Chiozzi:

Please refer to your supplemental new drug application dated, September 29, 2004 received September 30, 2004 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for REYATAZ (atazanavir) tablets.

This supplemental new drug application provides for changes in the Carcinogenesis, Mutagenesis, and Impairment of Fertility section of the label.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling for the package insert submitted September 29, 2004.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Vasavi Reddy, RPh, Regulatory Project Manager, at (301) 827-2413.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office Drug Evaluation IV
Food and Drug Administration

Attachment:

FPL

**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
10/5/04 05:39:36 PM