



NDA 20-972/S-031
NDA 21-360/S-018

Bristol-Myers Squibb Company
Attention: Katherine Takaki
Director, Global Regulatory Science
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

Dear Ms. Takaki:

Please refer to your supplemental new drug applications dated April 16, 2008, received April 16, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Sustiva® (efavirenz) 50 mg and 200 mg capsules and Sustiva® (efavirenz) 600 mg tablets.

We acknowledge receipt of your submissions dated:

July 3, 2008	September 3, 2008	November 13, 2008
January 16, 2009	March 6, 2009	

These supplemental new drug applications provide for the following revisions:

1. Reformat PI and PPI to the Physician Labeling Rule format.
2. Delete the terms “nail disorders” and “skin discoloration” from the POSTMARKETING section.
3. Update information regarding increasing levels of lipids in 17.9 FDA-Approved Patient Labeling for consistency with PI.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the enclosed labeling (text for the package insert and patient package insert).

CONTENT OF LABELING

Within 14 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] 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 and verification, we will transmit that version to the National Library of Medicine for public dissemination.

In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in structured product labeling (SPL) format to include the changes approved in these applications.

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

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 Jaewon Hong, PharmD, Regulatory Project Manager, at (301) 796-2013.

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: Package Insert
Patient Package Insert

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

/s/

Kendall Marcus
3/10/2009 08:42:31 AM