DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-972 SLR-035
NDA 21-360 SLR-023

SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company
Attention: Katherine Takaki, Ph.D.
Director, Global Regulatory Strategy
5 Research Parkway
Wallingford, CT 06492

Dear Dr. Takaki:

Please refer to your supplemental new drug applications dated and received December 4, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sustiva® (efavirenz) 50 mg and 200 mg capsules, and 600 mg tablets.

We acknowledge receipt of your submission dated February 22, 2010.

These Prior Approval supplemental new drug applications provide for the following revisions:

- the WARNINGS and PRECAUTIONS and the Postmarketing Experience sections of the package insert (PI) and the "What are the possible side effects of SUSTIVA?" section of the patient package insert (PPI) to include information on hepatotoxicity;

- the Drug Interactions section of the PI and the PPI was updated to include information on the coadministration of Sustiva with maraviroc and posaconazole; and

- the number of patients enrolled in the Antiretroviral Pregnancy Registry was updated based on the July 2009 annual report.

We have completed our review of these applications. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text, which is identical to the content labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling(SPL) format submitted on February 22, 2010.

CONTENT OF LABELING

Please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 20-972/S-035 and 21-360/S023**."

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.

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, please contact Venessa M Perry, MPH, Regulatory Project Manager, at 301.796.4891.

Sincerely,

{See appended electronic signature page}
/Kendall Marcus, MD/
for 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-21360	SUPPL-23	BRISTOL MYERS SQUIBB PHARMA CO	SUSTIVA (EFAVIRENZ) 300/600MG TABLETS
NDA-20972	SUPPL-35	BRISTOL MYERS SQUIBB CO	SUSTIVA

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

/s/

VENESSA M PERRY
03/31/2010

KENDALL A MARCUS
03/31/2010