DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-972/S-030
NDA 21-360/S-017

NDA APPROVAL

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 application dated March 12, 2008, received March 12, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Sustiva® (efavirenz) 50mg, 100mg and 200mg capsules and Sustiva® (efavirenz) 600mg tablets.

These supplemental new drug applications provide for the following revisions to the labeling: Add a recommendation to continue contraception for 12 weeks after discontinuation of efavirenz; Update the Antiretroviral Pregnancy Registry data based on the most recent Antiretroviral Pregnancy Registry report dated December 2007; Add the term "cerebellar coordination and balance disturbances" to the post-marketing experience section; And delete the 100 mg capsule, which BMS is no longer marketing.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March 12, 2008.

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.
Division Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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

8/18/2008 03:19:53 PM