DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-972/S-026
NDA 21-360/S-013

Bristol-Myers Squibb
Attn: Lori A. DeVore, BS
Associate Director, Antiviral Products
Global Regulatory Strategy
P.O. Box 5100
5 Research Parkway
Wallingford, CT 06492

Please refer to your supplemental new drug applications dated January 5, 2005, received January 6, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SUSTIVA® (efavirenz) Capsules and SUSTIVA® (efavirenz) Tablets.

We acknowledge receipt of your submission(s) dated January 6, 2005, March 4, 2005, March 23, 2005, and March 24, 2005.

These "Changes Being Effected" supplemental new drug applications provide for the incorporation of new information in the SUSTIVA® (efavirenz) label regarding pregnancy, to include a change in the Pregnancy Category for SUSTIVA® (efavirenz) from "C" (Risk of fetal harm cannot be ruled out) to "D" (Positive evidence of fetal risk).

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 23, 2005

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, please call Destry Sillivan, M.S., Regulatory Project Manager, at (301) 827-2376.

Sincerely,

{See appended electronic signature page}

Jeffrey Murray, M.D., M.P.H.
Deputy Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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

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