DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-360/S-005
NDA 20-972/S-021

Bristol-Myers Squibb
Attention: Crystina Cupp, Ph.D.
Manager, Global Regulatory Science
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

Dear Dr. Cupp:

Please refer to your Special Supplements-Changes Being Effected, dated September 30, 2003 received October 1st, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SUSTIVA® (efavirenz) Capsules 50 mg, 100 mg, 200 mg and SUSTIVA® (efavirenz) Tablets 300mg and 600mg.

These supplemental new drug application provides a revision in the package insert to incorporate the labeling changes requested by FDA on June 2, 2003, in accordance with 21 CFR314.70(c)(2).

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

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

If you have any questions, please call Donald W. Reese, PharmD,MBA, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
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/

Debra Birnkrant
11/13/03 12:28:45 PM
NDA 21-360, 20-972