DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-972/S-019
NDA 21-360/S-004

Bristol-Myers Squibb
Attention: Marie-Laure Papi
Manager, Global Regulatory Science
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

Dear Ms. Papi,

Please refer to your supplemental new drug application(s) dated April 29, 2003, received April 30, 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 600 mg.

These "Changes Being Effected" supplemental new drug application(s) provides for inclusion of clinical data regarding birth defects in pregnant women who have been exposed to Sustiva®.

We have completed our review of these supplemental new drug application(s). They are approved, effective on the date of this letter, for use as recommended in the final draft printed labeling submitted on April 29, 2003.

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, call Sylvia D. Lynche, Pharm.D., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra B. Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV

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
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NDA 20-972, 21-360