



NDA 20-972/S-018
NDA 21-360/S-003

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 May 23 2003, received April 30, 2003 and June 3, 2003, received June 3, 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 supplemental new drug application(s) provides for revisions under the following sections: **CLINICAL PHARMACOLOGY and Drug Interactions** (see also **CONTRAINDICATIONS** and **CLINICAL PHARMACOLOGY: Drug Interactions**).

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 May 23, 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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