Dear Ms. Papi,

Please refer to your supplemental new drug application(s) dated May 23 2003, received April 30, 2003 and 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
6/10/03  04:38:31 PM
NDA 20-972, 21-360