NDA 20-972

DuPont Pharmaceuticals Company
Attention: Richard Levy, M.D.
Chestnut Run Plaza
974 Centre Road
Wilmington, DE 19805

Dear Dr. Levy:

Please refer to your June 11, 1998 new drug application, NDA 20-972 submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Sustiva™ (efavirenz), 50mg, 100mg, and 200mg capsules.

We acknowledge receipt of your submissions dated:

March 16, 1998	August 4, 1998	August 7, 1998
August 13, 1998	August 26,1998 (2)	August 28, 1998
September 3, 1998	September 4, 1998 (3)	September 9, 1998 (3)
September 10, 1998 (3)		

This new drug application provides for the use of efavirenz in combination with other antiretroviral agents for the treatment of HIV-1 infection.

We have completed the review of this application, as amended, according to the regulations for accelerated approval, and have concluded that adequate information has been presented to approve Sustiva (efavirenz) 50mg, 100mg, and 200mg capsules for use as recommended in the draft label dated September 17, 1998. Accordingly, the application is approved under 21 CFR Subpart H. Approval is effective on the date of this letter. Marketing of this drug product and related activities are to be in accordance with the substance and procedures of the referenced accelerated approval regulations.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert). Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit sixteen copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-972. Approval of this submission by FDA is not required before the labeling is used.

Products approved under the accelerated approval regulations, 21 CFR 314.510, require further adequate and well-controlled studies to verify and describe clinical benefit. We remind you of your post marketing studies (Subpart H) specified in your submission dated September 15, 1998, (b)(4)(CC)----------
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Final study reports should be submitted to this NDA as a supplemental application. For administrative purposes, all submissions relating to the Subpart H commitment must be clearly designated "Subpart H "

In addition, we note the following Phase 4 commitments, specified in your submission dated September 15, 1998. These commitments, along with any completion dates agreed upon, include:

(b)(4)(CC)----------

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Protocols, data, and final reports should be submitted to your IND for this product and a copy of

the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.81(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

We also remind you that, under 21 CFR 314.550, after the initial 120 day period following this approval, you must submit all promotional materials, including promotional labeling as well as advertisements, at least 30 days prior to the intended time of dissemination of the labeling or initial publication of the advertisement.

Validation of the regulatory methods has not been completed. At present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any deficiencies that may occur.

Please submit one market package of the drug when it is available.

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

If you have any questions, please contact Ms. Terrie L. Crescenzi, R.Ph., Regulatory Management Officer, at (301) 827-2335.

Sincerely yours,

M. Dianne Murphy, M.D.
Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research