DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-360

Bristol-Myers Squibb Pharma Company
Attention: Cynthia Piccirillo
Associate Director, Regulatory Science
5 Research Parkway
2 CW-1038
Wallingford, CT 06492

Dear Ms. Piccirillo:

Please refer to your new drug application (NDA) dated March 30, 2001, received April 2, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sustiva® (efavirenz) 300 mg and 600 mg tablets.

We acknowledge receipt of your submissions dated May 31, 2001, July 25, 2001, August 13, 2001, September 28, 2001, October 8, 2001 (2), November 12, 2001, December 12, 2001, December 13, 2001, December 21, 2001, January 3, 2002, January 11, 2002, January 18, 2002, January 29, 2002 (2) and January 31, 2002.

This new drug application provides for the use of Sustiva® (efavirenz) 300 mg and 600 mg tablets for the treatment of HIV-1 infection in combination with other antiretroviral agents.

We have completed the review of this application, 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 enclosed labeling text. Accordingly, the application is approved effective on the date of this letter. Per our discussions on January 17, 2002 and January 22, 2002, it is our understanding that you only intend to market the 600 mg (b)(4)----------
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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 the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be

designated "FPL for approved NDA 21-360." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitments, as agreed upon in the February 9, 2000 traditional approval of NDA 20-972.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). Based on the information submitted, we have concluded that a waiver is justified for Sustiva® (efavirenz) tablets and capsules for the treatment of HIV infection in pediatric patients three years of age and older. Results of pediatric studies to determine the appropriate dosage of other formulations of Sustiva® (efavirenz) for HIV-infected patients younger than five years of age are due to the Agency by June 30, 2003.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

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 Virginia Yoerg, 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

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jeffrey Murray
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