DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-972, S-022
NDA 21-360, S-006

Bristol-Myers Squibb
Attn: Crystina Cupp, Ph.D.
Manager, Global Regulatory Science
P.O. Box 5100
5 Research Parkway
Wallingford, CT 06492

Dear Dr. Cupp:

Please refer to your supplemental new drug applications dated October 10, 2003, received October 14, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SUSTIVA® (efavirenz) Capsules and SUSTIVA® (efavirenz) Tablets.

We acknowledge receipt of your submission(s) dated November 11, 2003, November 14, 2003, January 7, 2004, April 5, 2004, April 14, 2004, May 3, 2004, May 17, 2004, June 11, 2004, June 16, 2004, July 23, 2004, July 29, 2004, August 5, 2004, August 6, 2004, and August 12, 2004.

These supplemental new drug applications provide for the inclusion of safety and efficacy data through 168 weeks of therapy from study AI266006 to the SUSTIVA® (efavirenz) Capsules and SUSTIVA® (efavirenz) Tablets package inserts.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted August 12, 2004, patient package insert submitted August 12, 2004.)

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-972, S-022, NDA 21-360, S-006." Approval of these submissions by FDA is not required before the labeling is used.

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. We are deferring submission of your pediatric studies for ages three months to 16 years until October 31, 2005.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below:

> Continue with the development of a pediatric program, with emphasis on developing a liquid formulation along with obtaining safety, tolerability, pharmacokinetic and antiviral activity data. Additionally, we refer to our Pediatric Written Request letter.

Additionally, we remind you of your outstanding postmarketing commitments listed in the approval letter for NDA 20-972 for SUSTIVA® (efavirenz) Capsules dated February 9, 2000, numbers two, three, five, seven, and eight.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Destry M. Sillivan, M.S., 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

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 21-360, 20-972