DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-972/S-016

Bristol-Myers Squibb
Pharmaceutical Research Institute
Attn: Crystina Cole, Ph.D.
Manager, Global Regulatory Science
3 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

Dear Dr. Cole:

Please refer to your supplemental new drug application dated September 28, 2001, received October 1, 2001, 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 submission(s) dated April 25, 2002 and August 16, 2002.

This supplemental new drug application was submitted to revise the Sustiva? label by including statements regarding the occurrence of convulsions in both patients and animals and by including the results of carcinogenicity studies. These revisions can be found under the PRECAUTIONS General , CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT of FERTILITY, and Patient Information sections.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below/indicated in the enclosed labeling.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-972S-016" Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
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, call Sylvia D. Lynche, PharmD, Regulatory Management Officer, at (301) 827-2335.

Sincerely,

Debra B. Birnkrant, M.D.
Division Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV

{See appended electronic signature page}

Enclosure : Printed Labeling Submitted August 16, 2002 by Sponsor.

Keep SUSTIVA at room temperature (77?F) in the bottle given to you by your pharmacist. The temperature can range from 59? to 86?F.

Keep SUSTIVA out of the reach of children.

This leaflet summarizes the most important information about SUSTIVA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for the full prescribing information about SUSTIVA, or you can visit the SUSTIVA website at http://www.sustiva.com or call 1-800-426-7644.

*SUSTIVA? is a registered trademark of Bristol-Myers Squibb Pharma Company.

**The brands listed are the registered trademarks of their respective owners and are not trademarks of Bristol-Myers Squibb Company.

Distributed by:

Bristol-Myers Squibb Company

Princeton, NJ 08543 USA

xxxxxx/Rev. xxxxx, 2002