



NDA 20-972/S-017
NDA 21-360/S-001

Bristol-Meyers Squibb
Attention: Crystina Cole
Manager, Global Regulatory Science
5 Research Parkway
Wallingford, CT 06492

Dear Dr. Cole:

Please refer to your supplemental new drug applications dated May 17, 2002, received May 20, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sustiva[®] (efavirenz) 300 mg and 600 mg tablets, and 50mg, 100mg, 200mg capsules.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for changes to the Laboratory Abnormalities section.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted May 17, 2002, patient package insert submitted May 17, 2002). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, call Christine Lincoln, RN, MS, MBA, 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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