



NDA 20-972/S-007

Bristol-Myers Squibb Company  
Attention: Ms. Cynthia Piccirillo  
Associate Director, Regulatory Science  
5 Research Parkway  
Wallingford, CT 06492

Dear Ms. Piccirillo:

Please refer to your supplemental new drug application dated August 7, 2000, received August 8, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sustiva® (efavirenz).

We acknowledge receipt of your submissions dated October 18, 2000, April 18, 2001, June 5, 2001, June 28, 2001, September 6, 2001, December 20, 2001, January 3, 2002, January 18, 2002, January 29, 2002, and January 31, 2002.

This supplemental new drug application provides for identical label changes that were completed with the approval of NDA 21-360 on February 1, 2002.

We have completed the review of this supplemental 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 labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert and patient package insert submitted January 31, 2002).

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 supplement NDA 20-972/S-007." Approval of this submission by FDA is not required before the labeling is used.

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.

If you have any questions, call Virginia Yoerg, Regulatory Project Manager, at 301 827 2335.

Sincerely,

*{See appended electronic signature page}*

Debra B. 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  
3/1/02 02:48:33 PM  
NDA 20-972