CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-972 / S-014

Trade Name: Sustiva

Generic Name: (efavirenz)

Sponsor: Bristol Myers Squibb

Approval Date: February 28, 2002

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APPLICATION NUMBER:

20-972 / S-014

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Reviews / Information Included in this NDA Review.	
Approval Letter	X
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EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	

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APPLICATION NUMBER:

20-972 / S-014

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Antiviral Drug Products
Food and Drug Administration
Rockville MD 20857

NDA 20-972/S-014

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 supplemental new drug application dated August 30, 2001, received August 31, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SUSTIVA® (efavirenz) Capsules, 50, 100 and 200 mg.

This "Changes Being Effected" supplemental new drug application provides for addition

substance.

We have completed the review of this supplemental application and it is approved.

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 yours,

{See appended electronic signature page}

Stephen P. Miller, Ph.D.
Chemistry Team Leader for the
Division of Antiviral Drug Products, (HFD-530)
DNDC III, Office of New Drug Chemistry
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/

Stephen Paul Miller
2/28/02 01:44:52 PM
20-972 S-014 is approved

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APPLICATION NUMBER:

20-972 / S-014

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW	1. ORGANIZATION HFD-530	2. NDA NUMBER 20-972
3. NAME AND ADDRESS OF APPLICANT *(City and State)* Bristol-Myers Squibb Pharma Co. Chestnut Run Plaza 974 Centre Road Wilmington, DE 19805		4. AF NUMBER 5. DOCUMENT(S) NUMBER(S) SCM-014 DATE(S) 8/31/01
6. NAME OF DRUG Sustiva capsules	7. NONPROPRIETARY NAME Efavirenz	
8. SUPPLEMENT(S) PROVIDES FOR: Addition of a C]		9. AMENDMENTS AND OTHER *(Reports, etc.)* DATES
10. PHARMACOLOGICAL CATEGORY Anti-Retroviral	11. HOW DISPENSED |X| Rx | | OTC	12. RELATED IND/NDA/DMF(S)
13. DOSAGE FORM(S) capsule	14. POTENCY(IES) **50, 100, 200 mg**	
15. CHEMICAL NAME AND STRUCTURE See current package insert		16. MEMORANDA

17. COMMENTS

The sponsor is requesting addition of their [redacted] The supplement meets the criteria outlined under PAC-ATLS.

The [redacted] site was found acceptable as a release and stability tester by Compliance on 12/10/01, based on inspection (see Attachment).

18. CONCLUSIONS AND RECOMMENDATIONS

It is recommended that this supplemental application for [redacted]

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Dan Boring	*/see electronic signature/*	**02/13/02**

20. CONCURRENCE: HFD-830/SMiller */see electronic signature/*

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/s/

Dan Boring
2/20/02 10:36:54 AM
CHEMIST

Stephen Paul Miller
2/22/02 03:28:07 PM
CHEMIST