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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-972/S-001

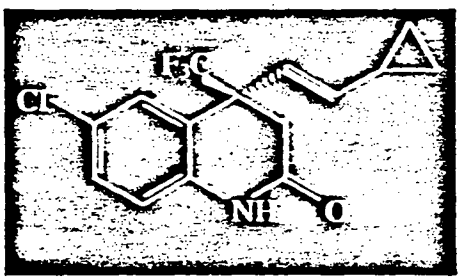
Pharmacology Review(s)

KELLY

PHARMACOLOGIST'S REVIEW

JUN 17 1999

NDA 20-972 Original NDA
Date Submitted: 5/26/99
Date Assigned: 6/4/99
Date Review Completed: 6/12/99
HFD-530



SPONSOR Dupont Co.
Wilmington, DE

DRUG Sustiva®; Efavirenz; DMP 266; L-743,726; (S)-6-chloro-4-(cyclopropylethynyl)-1,4-dihydro-4(trifluoromethyl)-2H-3,1-benzoxazin-2-one; $C_{14}H_9ClF_3NO_2$; MW: 315.7

FORMULATION Blue, —— . hard gelatin capsules filled with ——

Inactive Ingredients: sodium lauryl sulfate, NF; —— and sodium starch glycolate, NF.

COMMENTS TO THE SPONSOR: NO

INDICATION Treatment of HIV

COMMENTS: This NDA was granted an accelerated approval on 9/17/1998. In the current submission, the sponsor submitted additional clinical data (48 weeks treatment duration) for a full (traditional) approval of this NDA. There are no new pharm/tox data included in the submission and the wording of the pharm/tox portion of the new labelling remains unchanged. From the pharm/tox standpoint, this supplemental NDA is approvable. No regulatory comments on nonclinical safety will be provided for this supplemental NDA.

Kuei-Meng Wu, Ph.D.
Reviewing Pharmacologist
DAVDP

Concurrences:
HFD-530/DepDir/WDempsey 6/18/99
DAVDP/HFD-530/PTL/JFarrelly 6/17/99
Wu/Pharm/6/12/99 6/12/99
Disk: JFarrelly

HFD-530 NDA 20-972 (001)
HFD-530/Division File
HFN-340
HFD-530/CSO/ Kelly
HFD-530/MO / Haverkos
HFD-530/Pharm / Sekar