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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-972/S-001

Pharmacology Review(s)
PHARMACOLOGIST'S REVIEW

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_{9}ClF_{3}NO_{2}; MW: 315.7

FORMULATION
Blue, hard gelatin capsules filled with

Inactive Ingredients: sodium lauryl sulfate, NF;
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
DAVDP/HFD-530/PTL/JFarrelly
Wu/Pharm/6/12/99
Disk: JFarrelly

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