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APPLICATION NUMBER:
21-937

PHARMACOLOGY REVIEW(S)

PHARMACOLOGIST'S REVIEW

IND NUMBER: 21-937

NUMBER/DATE/TYPE: 000/1-17-2006

INFORMATION TO SPONSOR Yes () No (x)

SPONSOR Gilead Sciences, Foster City CA on behalf of Bristol-Myers Squibb & Gilead Sciences (a joint venture partnership for this fixed dose combination product)

REVIEWER NAME: Kuei-Meng Wu

DIVISION NAME: DAVDP

HFD #: HFD-530

REVIEW COMPLETION 5/25/06

DRUG TRADE NAME: — (efavirenz 600 mg, emtricitabine 200 mg, and tenofovir disoproxil fumarate 300 mg)

RELATED NDA Truvada[®] (emtricitabine+tenofovir, NDA 21-752)
Sustiva[®](efavirenz, NDA 20-972, Approved 9/1998; NDA 21-360, 2/2002)
Emitra[®] (emtricitabine, NDA 21-500, Approved 7/2003)
Viread[®] (tenofovir disoproxil fumarate , NDA 21-356, Approved 10/2001)

RELATED NDA 71,420/53,971/52,849/67,671/49,465/56,897

DRUG CLASS: Antiviral

INDICATION: Treatment of HIV infection

ROUTE Oral

PROPOSED USE: HIV Infection

INTRODUCTION Gilead Science (on behalf of Bristol-Myers Squibb & Gilead Sciences, a joint venture partnership for — , submitted an NDA for a new triple fixed dose combination for HIV infection which includes efavirenz 600 mg, emtricitabine 200 mg, and tenofovir disoproxil fumarate 300 mg. All preclinical information on — is cross-referenced to the original NDAs and INDs cited above and no additional pharm/tox information is included in the package (please see EDR files at \\Cdsub1\n21937\N_000\2006-01-13\N21937\labeling). From the Pharm/Tox perspectives, this NDA is recommended for approval. No changes in proposed labeling and no pharm/tox regulatory comments are needed for this NDA.

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

Concurrences:
HFD-530/Dep Dir/JFarrelly
Wu/Pharm/5/25/06

Disk: HFD-530/JFarrelly

cc:
HFD-530 IND 21-937 (000)
HFD-530/Division File
HFN-340
HFD-530/CSO/
HFD-530/Pharm/

**APPEARS THIS WAY
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/s/

Kuei Meng Wu
5/30/2006 09:33:39 AM
PHARMACOLOGIST

James Farrelly
5/30/2006 11:16:27 AM
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