CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER  20-972

CHEMISTRY REVIEW
DIVISION OF ANTIVIRAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA#: 20-972

CHEMISTRY REVIEW #: 1 DATE REVIEWED: 6/29/98

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NAME & ADDRESS OF SPONSOR: DuPont Merck Pharmaceutical Company
DuPont Merck Plaza
Centre Road
Wilmington, DE 19805

DRUG PRODUCT NAMES:
Proprietary Sustiva™
Nonproprietary efavirenz
Code Name DMP 266

PHARMACOLOGICAL CATEGORY: Antiretroviral

INDICATION: HIV

DOSAGE FORM/STRENGTH: capsule/ 50, 100, 200 mg

ROUTE OF ADMINISTRATION: oral

CHEMICAL NAME/STRUCTURAL FORMULA:

(S)-6-Chloro-4-(cyclopropylethynyl)-1,4-dihydro-(trifluoromethyl)-2H-3,1-benzoazin-2-one

Molecular Formula: C_{14}H_{9}ClF_{3}NO_{2}
SUPPORTING DOCUMENTS:

(b)(4)

RELATED DOCUMENTS:

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<td>Final drug substance and drug product specifications</td>
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CONCLUSIONS & RECOMMENDATIONS:

This application, as amended, is in conformance with section 505(b) in relation to chemistry manufacturing and controls procedures and may be approved from this standpoint. The product is to carry an 18 month expiration date.

Dan Boring, R.Ph., Ph.D., Review Chemist for HFD-530

Concurrence:
HFD-530-/SMiller

cc:
NDA 20-972 Original       HFD-530/DBoring       HFD-530/TCrescenzi
HFD-530 Division File      HFD-530/SMiller       HFD-530/HHaverkos
HFD-830/CChen              HFD-530/SKukich       HFD-530/KMWu
HFD-530/VSekar             HFD-530/LIacono-Connors