CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-453

Pharmacology Review(s)

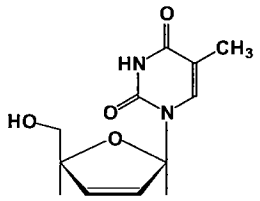
PHARMACOLOGY/TOXICOLOGY COVER SHEET

NDA number: 21-453 (000)
Sequence number/date/type of submission: 000/March 15, 2002/original
Information to sponsor: Yes ( ) No (x)
Sponsor and/or agent: Bristol-Myers Squibb Company
P.O. Box 5400
Princeton, NJ 08540

Reviewer name: C. Anita H. Bigger, PhD
Division name: Division of Antiviral Drug Products
HFD #: 530
Review completion date: December 5, 2002

Drug:

Trade name: Zerit XR
Generic name: Stavudine
Code name: BMY-27857 (d4T)
Chemical name: 2'3'-didehydro-3'-deoxythymidine
Structure:



Relevant INDs/NDAs/DMFs: NDA 20-412

Drug class: Nucleoside analogue HIV reverse transcriptase inhibitor

Indication: Treatment of HIV infection in combination with other antiretrovirals.

Clinical formulation: Extended release capsules of 37.5, 50, 75 and 100 mg.

Route of administration: Oral

COMMENTS

Zerit is an approved drug (NDA 20-412) for treatment of HIV infection. The present NDA is for Zerit in an extended release formulation. No new pharmacology/toxicology data were submitted with this NDA. There were no proposed labeling changes in the pharmacology/toxicology sections of the label. There are no pharmacology/toxicology issues with this NDA.

Reviewer signature: _____

Supervisor signature: Concurrence - _____

cc: list:

HFD-530 Original IND
HFD-530 Division File
HFD-340
HFD-530/KMarcus
HFD-530/LMishra
HFD-530/KLo
HFD-530/ABigger
HFD-530/JZheng
HFD-530/SZhou
HFD-530/SLynche

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/s/

Anita Bigger
12/13/02 09:59:22 AM
PHARMACOLOGIST

James Farrelly
12/13/02 10:04:38 AM
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