CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

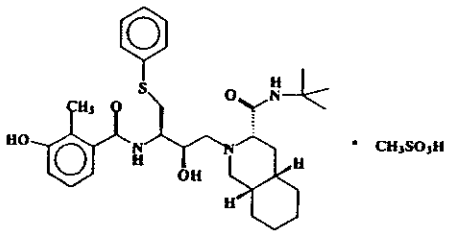
21-503

PHARMACOLOGY REVIEW(S)

PHARMACOLOGY/TOXICOLOGY COVER SHEET

NDA number:	21-503
Review number:	001
Sequence number/date/type of submission:	000/June 28, 2002/Ori
Information to sponsor:	Yes ( ) No (X)
Sponsor and/or agent:	Agouron Pharmaceuticals, Inc.
Manufacturer for drug substance :	Agouron Pharamceuticals, Inc
Reviewer name:	Ita Yuen
Division name:	Division of Antiviral Drug Products
HFD #:	530
Review completion date:	April 11, 2003

Drug:

Trade name:	VIRACEPT®
Generic name (list alphabetically):	Nelfinavir mesylate
Code name:	AG1343 (salt); AG1346 (free base)
Chemical name:	[3S-[2(2S*,3S*,3α,4aβ, 8aβ]]-N-(1,1-dimethylethyl) decahydro-2-[2-hydroxy-3-[(3-hydroxy-2-methylbenzoyl)amino-4-(phenylthio)butyl]-3-isoquinolinecarboxamide, monomethanesulfonate (salt)
CAS registry number:	159989-65-8 for AG1343 159989-64-7 for AG1346
Mole file number:	N/A
Molecular formula/molecular weight:	$C_{32}H_{45}N_3O_4S \bullet CH_4$ 663.90 for AG1343; 567.79 for AG1346
Structure:	

Relevant INDs/NDAs/DMFs:	IND 48,124, NDA 20-778, 20-779
Drug class:	HIV protease inhibitor
Indication:	Treatment of HIV infection
Clinical formulation:	625 mg oral tablets containing 730.6 mg nelfinavir mesylate (equivalent to 625 mg nelfinavir free base), calcium silicate, crospovidone, colloidal

silicon dioxide, magnesium stearate.

Route of administration:	Oral
Proposed use:	1250 mg BID

Disclaimer: Tabular and graphical information is from sponsor's submission unless stated otherwise.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability

Nelfinavir mesylate was approved for marketing for the treatment of HIV-1 infection. The recommended dosing regimen was 750 mg TID and 1250 mg BID. To reduce the pull burden for the patients, the sponsor has developed a new formulation containing 625 mg nelfinavir/tablet. The sponsor is seeking the approval of this new formulation to complement the 1250 mg BID regimen. There are no nonclinical pharmacology/toxicology issues that affect the approvability of this supplement.

B. Recommendation for Nonclinical Studies

Not applicable.

C. Recommendations on Labeling

There is no new information and thus no change to "Carcinogenesis, Mutagenesis, Impairment of Fertility" and "Pregnancy Category" sections.

II. Summary of Nonclinical Findings

A. Brief Overview of Nonclinical Findings

Not applicable.

B. Pharmacologic Activity

Not applicable.

C. Nonclinical Safety Issues Relevant to Clinical Use

Not applicable.

III. Administrative

A. Reviewer signature: _____

B. Supervisor signature: Concurrence - _____

cc: list: HFD-530/NDA 21,503 (000)
HFD-530/Division File
HFD-530/JO'Neil
HFD-530/NGibbs
HFD-530/GLunn

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/s/

Ita Yuen
4/11/03 02:05:05 PM
PHARMACOLOGIST

James Farrelly
4/14/03 01:12:46 PM
PHARMACOLOGIST

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