CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-779 / S-035

Trade Name: Viracept

Generic Name: (nelfinavir mesylate)

Sponsor: Pfizer Inc.

Approval Date: October 26, 2001

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APPLICATION NUMBER:

20-779 / S-035

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EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
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Administrative and Correspondence Document(s)	

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APPLICATION NUMBER:

20-779 / S-035

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-779/S-035

Agouron Pharmaceuticals, Inc.
Attention: Paul R. Chen, Ph.D.
10350 North Torrey Pines Road
La Jolla, CA 92037-1020

Dear Dr. Chen:

Please refer to your supplemental new drug application dated July 13, 2001, received July 16, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIRACEPT® (nelfinavir mesylate) Tablets, 250 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for qualification of [redacted] as a manufacturing site for nelfinavir mesylate tablets.

We have completed the review of this supplemental application, and it is approved. A 36-month expiration dating period is acceptable for tablets manufactured at the Gödecke facility.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sean J. Belouin, R.Ph., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Stephen P. Miller, Ph.D.
Chemistry Team Leader for the
Division of Antiviral Drug Products, (HFD-530)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Stephen Paul Miller
10/26/01 04:26:45 PM
20-779 S-035 is approved.

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APPLICATION NUMBER:

20-779 / S-035

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW	DUE DATE 1/16/02	1. ORGANIZATION HFD-530	2. NDA NUMBER 20-779

3. NAME AND ADDRESS OF APPLICANT
Agouron Pharmaceuticals, Inc.
10350 North Torrey Pines Road
La Jolla, CA 92037-1022
Attn: Paul R. Chen, Ph.D.

4. TYPE OF SUPPLEMENT
CBE-30

5. DOCUMENT(S)

NUMBERS	DATED	RECEIVED
SCM-035	7/13/01	7/16/01

6. NAME OF DRUG
VIRACEPT[R] Tablets

7. NONPROPRIETARY NAME
nelfinavir mesylate tablets

8. SUPPLEMENT PROVIDES FOR:
The qualification [redacted] facility in [redacted] as a manufacturing site for nelfinavir mesylate tablets

9. AMENDMENTS/DATES

10. PHARMACOLOGICAL CATEGORY
Anti-HIV

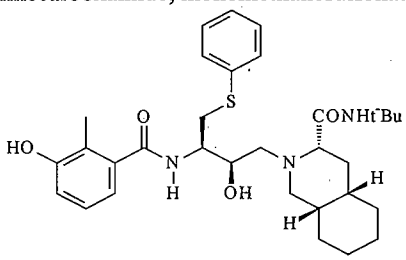
11. HOW DISPENSED
|X| Rx | | OTC

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(S)
Tablets

14. POTENCY (CIES)
250 mg

15. CHEMICAL NAME AND STRUCTURE
[3S-[2(2S*,3S*,3α,4aβ,8aβ]]-N-(1,1-dimethylethyl)decahydro-2-[2-hydroxy-[(3-hydroxy-2-methylbenzoyl)amino-4-(phenylthio)butyl]-3-isoquinolinecarboxamide, monomethanesulfonate (salt)



CH_3SO_3H

16. MEMORANDA

17. COMMENTS
In this CBE-30 supplement the sponsor wishes to qualify the [redacted] as a manufacturer of nelfinavir mesylate tablets. An Establishment Evaluation Request was submitted and a recommendation of "acceptable" was made by the Office of Compliance. The composition of the tablets, manufacturing process, in-process controls, tests, analytical methods, acceptance criteria, and packaging system are not changed. The batch size lies within the approved batch sizes at the other manufacturing sites [redacted]. The equipment used a[redacted] of the same class and operating principle as the equipment used at the other [redacted]. he manufacturing parameters used [redacted] are close to or within the ranges used [redacted] n particular, the drying temperatures are the same as those used before. Three lots manufactured at [redacted] compared with lots manufactured at [redacted] Similar dissolution profiles are obtained. Three months of satistactory accelerated and room temperature data are reported for one lot manufactured at [redacted] Monitoring will continue to 36 months. Comparison data are provided for tablets manufactured at [redacted] first 3 commercial validation lots will be placed on accelerated and long-term stability. Sinc[redacted] atches of coated tablets have been manufactured a significant body of data is available and hence the requirements of SUPAC-IR are fulfilled. Based on these data an expiration date of 36 months (currently approved for tablets manufactured at [redacted] reasonable.

18. CONCLUSIONS AND RECOMMENDATIONS
This Supplement is therefore recommended for approval.

19. REVIEWER

NAME	SIGNATURE	DATE OF DRAFT REVIEW
George Lunn, Ph.D.	*[signed electronically in DFS]*	9/7/01

20. CONCURRENCE: HFD-530/SMiller *[signed electronically in DFS]*

DFS CC LIST										
L = Action Letter	R	L	SMiller	R	L	PM: SBelouin			Micro	
		L	GLunn		L	Med: KLaessig			PharmTox	

WITHHOLD 7 PAGE(S)

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Chemistry Review 1a