CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-778 / S-015

Trade Name: Viracept

Generic Name: (nelfinavir mesylate)

Sponsor: Pfizer Inc.

Approval Date: December 21, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-778 / S-015

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Reviews / Information Included in this NDA Review.	
Approval Letter	X
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Medical Review(s)	
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	

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APPLICATION NUMBER:

20-778 / S-015

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-778/S-015

Agouron Pharmaceuticals, Inc.
Attention: Paul R. Chen, Ph.D.
10350 North Torrey Pines Road
La Jolla, CA 92037-1022

Dear Dr. Chen:

Please refer to your supplemental new drug application dated July 27, 2001, received July 30, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIRACEPT® (nelfinavir mesylate) Oral Powder, 50 mg/g.

This "Changes Being Effected in 30 days" supplemental new drug application, submitted under PAC-ATLS, provides for qualification of [redacted] s an additional [redacted]

We have completed the review of this supplemental application, and it is approved.

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
12/21/01 05:22:07 PM
20-778 S-015 is approved

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-778 / S-015

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW	DUE DATE 1/30/02	1. ORGANIZATION HFD-530	2. NDA NUMBER 20-778

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-015	7/27/01	7/30/01

6. NAME OF DRUG
VIRACEPT[R] Oral Powder

7. NONPROPRIETARY NAME
nelfinavir mesylate oral powder

8. SUPPLEMENT PROVIDES FOR:
The qualification of [redacted] as an a[redacted] C-ATLS

9. AMENDMENTS/DATES

10. PHARMACOLOGICAL CATEGORY
Anti-HIV

11. HOW DISPENSED
[X] Rx [ ] OTC

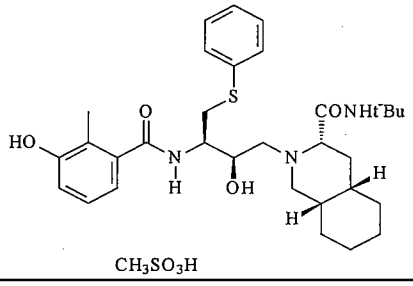
12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(S)
Tablets

14. POTENCY (CIES)
50 mg/g

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 submitted under PAC-ATLS the four requirements set by the Guidance, i.e., the approved test methods are used, all postapproval commitments have been fulfilled, the new testing facility has the capability to perform the intended testing, and the new testing facility has had a satisfactory current good manufacturing practice (cGMP) inspection within the past 2 years, are met. In addition, an Establishment Evaluation Request was submitted and a recommendation of "acceptable" was made by the Office of Compliance.

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

19. REVIEWER

NAME	SIGNATURE	DATE OF DRAFT REVIEW
George Lunn, Ph.D.	*[signed electronically in DFS]*	9/10/01

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

DFS CC LIST								
L = Action Letter	R	L	Smiller	R	L	PM: SBelouin		Micro
R = Review	R	L	ONDC3_IO (CChen)			Biopharm		
		L	GLunn		L	Med: KLaessig		PharmTox

WITHHOLD 2 PAGE(S)

b4

Chemistry Review 1a

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/s/

George Lunn
9/17/01 10:50:55 AM
CHEMIST

PAC-ATLS for nelfinavir oral powder

Stephen Paul Miller
9/26/01 03:32:55 PM
CHEMIST