

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-779 / S-036

Trade Name: Viracept

Generic Name: (nelfinavir mesylate)

Sponsor: Pfizer Inc.

Approval Date: October 26, 2001

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APPLICATION NUMBER:

20-779 / S-036

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APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-779/S-036

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 30, 2001, received July 31, 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 _____ as additional testing sites for nelfinavir mesylate tablets and P _____ as an additional testing site for nelfinavir mesylate drug substance.

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

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this page is the manifestation of the electronic signature.**

/s/

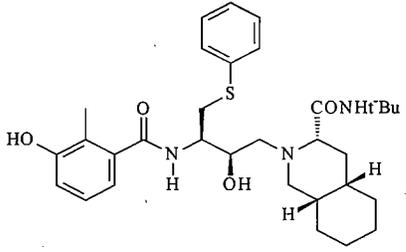
Stephen Paul Miller
10/26/01 05:19:19 PM
NDA 20-779 S-036 is approved.

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APPLICATION NUMBER:

20-779 / S-036

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW		DUE DATE 1/31/02	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-036	7/30/01	7/31/01
6. NAME OF DRUG VIRACEPT [®] Tablets			7. NONPROPRIETARY NAME nelfinavir mesylate tablets		
8. SUPPLEMENT PROVIDES FOR: The qualification of _____ _____ Germanv as additional testing sites for nelfinavir mesylate tablets as an additional testing site for nelfinavir mesylate drug substance, all under _____			9. AMENDMENTS/DATES		
10. PHARMACOLOGICAL CATEGORY Anti-HIV		11. HOW DISPENSED <input checked="" type="checkbox"/> R <input type="checkbox"/> 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,4αβ,8αβ)]-N-(1,1-dimethylethyl)decahydro-2-[2-hydroxy-[(3-hydroxy-2-methylbenzoyl)amino-4-(phenylthio)butyl]-3-isoquinolinecarboxamide, monomethanesulfonate (salt)			16. MEMORANDA		
 <p style="text-align: center;">CH₃SO₃H</p>					
17. COMMENTS In this CBE-30 Supplement submitted under _____ the four requirements set by the Guidance, i.e., _____ methods are used, all postapproval commitments have been fulfilled, the _____ as the capability to perform the intended _____ has had a satisfactory current good manufacturing practice (cGMP) inspection within the past 2 years, are met for each site. 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 George Lunn, Ph.D.		SIGNATURE [signed electronically in DFS]		DATE OF DRAFT REVIEW 9/10/01	
20. CONCURRENCE: HFD-530/SMiller [signed electronically in DFS]					
DFS CC LIST	<input type="checkbox"/> L	GLunn	<input type="checkbox"/> L	Med: KLaessig	<input type="checkbox"/> PharmTox
L = Action Letter	<input type="checkbox"/> R	SMiller	<input type="checkbox"/> R	PM: SBelouin	<input type="checkbox"/> Micro
R = Review	<input type="checkbox"/> R	ONDC3 IO (CChen)	<input type="checkbox"/>	Biopharm	<input type="checkbox"/>

WITHHOLD 2 PAGE(S)

BA

Chemistry Review 1a

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/s/

George Lunn
9/17/01 10:48:13 AM
CHEMIST

PAC-ATLS for nelfinavir DS and DP

Stephen Paul Miller
9/27/01 12:21:32 PM
CHEMIST