CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020779, S022

Trade Name: VIRACEPT

Generic Name: NELFINAVIR MESYLATE

Sponsor:ARGOURON PHARMACEUTICALS, INC

Approval Date: 11/24/99

INDICATION(s):TREATMENT OF HIV INFECTION

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APPLICATION for: 020779, S022

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Chemistry Review(s)	X			
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Microbiology Review(s)	X			
Clinical Pharmacology Biopharmaceutics Review(s)	X			
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Application Number: **020779, S022**

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20778/S-011
NDA 20779/S-022

NOV 24 1999

Agouron Pharmaceuticals, Inc.
Attention: Patricia Rizun
Senior Regulatory Affairs Specialist
10350 North Torrey Pines Road
La Jolla, CA 92037-1020

Dear Ms. Rizun:

Please refer to your supplemental new drug applications dated January 26, 1999, received January 28, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIRACEPT® (nelfinavir mesylate) Oral Powder 50 mg/g and VIRACEPT® (nelfinavir mesylate) Tablet 250 mg.

The User Fee goal date for this application is January 28, 2000.

We acknowledge receipt of your submissions dated:

March 12, 1999	August 20, 1999	November 18, 1999
March 26, 1999	September 28, 1999 (2)	November 23, 1999 (3)
May 4, 1999	October 1, 1999	
June 16, 1999	November 4, 1999	
June 24, 1999	November 11, 1999	

These supplemental new drug applications provide for a 1250 mg twice daily dosing regimen of VIRACEPT® in combination with other antiretroviral therapies as an alternate dosing regimen for the standard VIRACEPT® dosing regimen of 750 mg three times daily in combination with other antiretrovirals for the treatment of HIV infection.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted draft labeling (package insert submitted November 24, 1999, patient package insert submitted November 24, 1999). Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert) submitted November 24, 1999.

Please submit 20 copies and a .pdf file of the FPL to each application as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on

heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FINAL PRINTED LABELING" for approved supplements NDA 20778/S-011 and 20779/S-022. In addition, please submit an electronic copy of the label in MS Word. Approval of these submissions by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitments specified in your submission dated November 22, 1999. These commitments, along with the completion dates agreed upon, are listed below.

1. A commitment to submit a final report of study 542 with full analyses of efficacy and safety to the Division of Antiviral Drug Products (DAVDP) for review by the end of 2000.

2. A commitment to evaluate pharmacokinetic parameters of twice a day dosing with the oral powder formulation of VIRACEPT® in pediatric patients by the end of 2000.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Please be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have not fulfilled all the requirements of 21 CFR 314.55 (or 601.27), and therefore we are deferring submission of your pediatric studies until July 1, 2001.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). Please refer to the Pediatric Written Request dated May 26, 1999. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity.