DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-778/SLR-020
NDA 20-779/SLR-041
NDA 21-503/SLR-002

Agouron Pharmaceuticals, Inc.
Attention: Marie-Dominique Mompas, PharmD.
Director, Regulatory Strategy
10777 Science Center Drive
San Diego, CA 92121

Dear Dr. Mompas:

Please refer to your supplemental new drug applications listed below, dated February 4, 2003, received February 5, 2003, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act:

NDA#	Drug Product	Supplement number
20-779	Viracept (nelfinavir mesylate) 250 mg tablets	041
20-778	Viracept (nelfinavir mesylate) 50 mg oral powder	020

We acknowledge receipt of your submissions to the above NDAs dated:

May 8, 2003
July 31, 2003

Please also refer to your supplemental new drug application listed below, dated August 6, 2003, received August 7, 2003, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act:

NDA#	Drug Product	Supplement number
21-503	Viracept (nelfinavir mesylate) 625 mg tablets	002

We have completed our review of these applications as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the Patient Package Insert submitted May 8, 2003 and Package Insert submitted July 31, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDAs (January 1999) as soon as it is available, in no case more than 30 days after it is printed to each application. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-778/S-020, NDA 20-779/S-041, and NDA 21-503/S-002." Alternatively, you may submit 20 paper copies of the FPL. Please mount individually ten of the copies on heavyweight paper or similar material. Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of each drug product when it is available

We remind you that you must comply with reporting requirements for an approved NDA (21 CDR 314.80 and 314.81).

If you have any questions, call Jeff O'Neill, ACRN, Regulatory Project Manager, at (301) 827-2362.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Division Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure (Labeling Attached)

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

/s/

Jeffrey Murray
8/27/03 04:39:47 PM