NDAs 20-778/S-024
        20-779/S-045
        21-503/S-006

Agouron Pharmaceutical Inc., A Pfizer Company
Attention: Justine King, Regulatory Manager
US Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. King:

Please refer to your supplemental new drug applications dated August 31, 2005, received September 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viracept (nelfinavir mesylate) 50mg/g Oral Powder, Viracept (nelfinavir mesylate) 250mg Tablets, and Viracept (nelfinavir mesylate) 625mg Tablets.

These "Changes Being Effected" supplemental new drug applications provide for the addition of drug-drug interactions and statements regarding immune reconstitution syndrome to the PRECAUTIONS section of the label.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 31, 2005.

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

> MEDWATCH, HFD-410
> FDA
> 5600 Fishers Lane
> Rockville, MD 20857

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 Elizabeth Thompson, Regulatory Project Manager, at (301) 796-0824.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Division Director
Division of Anti-Viral Products
Center for Drug Evaluation and
Research

Enclosure: Final Printed Labeling (FPL)

/s/

Debra Birnkrant
9/28/2005 08:59:34 AM
NDA 21-503, 20-778, 20-779