DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-778/S-014
NDA 20-779/S-032

Agouron Pharmaceuticals, Inc.
Attention: Marie-Dominique Mompas, PharmD.
Associate Director, Worldwide Regulatory Affairs
10350 North Torrey Pines Road
La Jolla, CA 92037-1020

Dear Ms. Mompas:

Please refer to your supplemental new drug applications dated January 26, 2001, received January 29, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viracept© (nelfinavir mesylate) 250mg tablets and 50mg/g oral powder.

We acknowledge receipt of your amended submissions dated March 23, 2001, received March 26, 2001.

These "Changes Being Effected" supplemental new drug applications provide for alerting patients of the need to find out about potential drug interactions with Viracept. This was accomplished through your participation in an implementation of a risk communication strategy to reduce the potential for serious and life-threatening drug interactions in patients receiving antiretroviral therapy for HIV. These changes have been incorporated into container labeling, the professional package insert (PI) and the patient package insert (PPI):

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 final printed labeling (package insert submitted March 23, 2001, patient package insert submitted March 23, 2001, immediate container and carton labels submitted January 26, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

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

Please submit one market package for each drug product when they are available.

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}

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

Attachment