



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-778/S-029
NDA 20-779/S-050
NDA 21-503/S-011

Agouron Pharmaceuticals Inc., A Pfizer Company
Attention: Robert B. Clark
Vice President U.S. Regulatory Affairs
235 East 42nd Street
New York, New York 10017-5755

Dear Mr. Clark:

Please refer to your supplemental new drug applications dated August 24, 2007, received August 25, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIRACEPT® (nelfinavir mesylate) 50 mg/g oral powder, VIRACEPT® (nelfinavir mesylate) 250 mg tablets and VIRACEPT® (nelfinavir mesylate) 625 mg tablets.

These supplemental new drug applications provide for revisions to the PRECAUTIONS section of the package inserts to add a rosuvastatin drug-drug interaction to Table 11 entitled "Established and Other Potentially Significant Drug Interactions".

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

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

If you have any questions, call Anne Marie Russell, Regulatory Project Manager, at (301) 796-2014.

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Sincerely,

{See appended electronic signature page}

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

Enclosure: Approved Draft Labeling (Package Insert)

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

/s/

Debra Birnkrant
2/13/2008 02:21:23 PM
NDA 21-503, 20-779, 20-778