DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20778/S36
NDA 20779/S57
NDA 21503/S18

SUPPLEMENT APPROVAL

Agouron Pharmaceuticals, Inc, A Pizer Company
Attention: Nadia Kirzecky
Director, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Kirzecky:

Please refer to your Supplemental New Drug Applications (sNDA) dated October 06, 2011, received October 07, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Viracept (nelfinavir mesylate) Oral Powder, 250 mg tablets, and 625 mg tablets.

We also refer to our approval letter dated April 06, 2012 which contained the following error: A typographical error was made under section "DOSAGE FORMS AND STRENGTHS" of the "HIGHLIGHTS OF PRESCRIBING INFORMATION" section of the Package Insert; the second dosage strength should have been 625 mg instead of 650 mg:

----------**DOSAGE FORMS AND STRENGTHS**----------
· Tablet: 250 mg, 650 mg nelfinavir free base (3)

The above should be corrected to:
----------**DOSAGE FORMS AND STRENGTHS**----------
· Tablet: 250 mg, 625 mg nelfinavir free base (3)

This replacement approval letter incorporates the correction of the error. The effective approval date will remain April 06, 2012, the date of the original approval letter.

We acknowledge receipt of your amendment dated April 5, 2012.

These Prior Approval Supplemental new drug applications propose:

- conversion of the labeling (package insert) to the Physician Labeling Rule (PLR) format
- addition of rifampin and cisapride to CONTRAINDICATIONS, Table 3
- specification of oral midazolam under CONTRAINDICATIONS, Table 3
- addition of safety information from a study of the effects of nelfinavir on QT intervals to the CLINICAL PHARMACOLOGY, Pharmacodynamics subsection
- revision to the Patient Package Insert to current standards

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

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert and text for the patient package insert, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROMOTIONAL MATERIALS

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

REPORTING REQUIREMENTS

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 Sohail Mosaddegh, PharmD, regulatory project manager, at (301) 796-4876 or (301) 796-1500.

Sincerely yours,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling (corrected):

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

/s/

KENDALL A MARCUS
04/06/2012