



NDA 20-778, S-016
NDA 20-778, S-017
NDA 20-779, S-037
NDA 20-779, S-038

Agouron Pharmaceuticals, Inc.
Attention: Marie-Do Mompas
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 August 15, 2001, received August 16, 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 September 25, 2001, September 28, 2001, and January 9, 2002.

These "Changes Being Effected" supplemental new drug applications provide for updated information on proper storage conditions for VIRACEPT Oral Powder.

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 September 25, 2001, patient package insert submitted September 25, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

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.

Director

Division of Antiviral Drug Products

Office of Drug Evaluation IV

Center for Drug Evaluation and Research

**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
2/5/02 02:25:53 PM
NDA 20-778, 20-779