DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-705/S-009

Agouron Pharmaceuticals Inc.
Attention: Stephen Sherman
Director, Regulatory Strategy
Worldwide Regulatory Affairs
10350 North Torrey Pines Road
La Jolla, CA 92037-1020

Dear Mr. Sherman:

Please refer to supplemental new drug application dated November 20, 2001, received November 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rescriptor® (delavirdine) 100 mg and 200mg Tablets.

This "Special Supplement-Changes Being Effected" supplemental new drug application provides for new precautionary language concerning fat redistribution.

We have completed the review of this supplemental new drug application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling dated November 20, 2001. We also acknowledge that the final printed labeling dated November 28, 2001 containing fat redistribution language is identical to the November 20, 2001 submission. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

Please submit one market package of the product when it is 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 question, call Sean Belouin, R.Ph., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra B. Birnkrant, M.D.
Division 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
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