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APPLICATION NUMBER:

20-705 / S-008

APPROVAL LETTER



NDA 20-705/S-008

Agouron Pharmaceuticals, Inc.
Attention: Matthew Moran
Manager, Regulatory Strategy and Registration
10350 North Torrey Pines Road
La Jolla, CA 92037

Dear Mr. Moran:

Please refer to your supplemental new drug application dated July 12, 2000, received July 17, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RESCRIPTOR[®] (delavirdine mesylate) 100mg and 200mg Tablets.

We acknowledge receipt of your submissions dated:

March 15, 2001	April 23, 2001
April 3, 2001	May 7, 2001
April 10, 2001	May 12, 2001
April 13, 2001	May 14, 2001
April 17, 2001	May 15, 2001

This NDA was approved under 21 CFR 314.510, the regulation for accelerated approval of new drugs for serious or life-threatening illnesses. This supplemental new drug application provides information to fulfill the accelerated approval commitments as required under 21 CFR 314.510. Specifically, this supplemental application provides for the use of RESCRIPTOR for the treatment of HIV-1 infection in combination with at least 2 other active antiretroviral agents when therapy is warranted.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text and with minor editorial revisions indicated in the enclosed labeling (deletions have a ~~strike through~~ and additions have an underline). Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert and immediate container labels). These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as requested, in the product's final printed labeling (FPL) may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-705/S-008." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your outstanding postmarketing study commitments that were outlined in the original accelerated approval letter dated April 4, 1997 and as updated in the facsimile dated May 14, 2001. We have also confirmed that the Phase IV clinical commitment number 2 in the facsimile dated May 14, 2001, which provides safety summary information for hemophiliac patients, has been completed.

Additionally, you agreed to the following Phase IV postmarketing commitments as outlined in your letter dated May 15, 2001:

1. Agouron agrees to conduct a pharmacokinetic study in subjects with hepatic impairment. A final report for this study is anticipated in fourth quarter of 2003.
2. Agouron agrees to conduct a drug interaction study of delavirdine with lopinavir/ritonavir. A final report for this study is anticipated in third quarter of 2002.
3. Agouron agrees to conduct a drug interaction study of delavirdine with low dose ritonavir. A final report for this study is anticipated in the second quarter of 2002.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **"Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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 of the drug 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 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

Enclosure