NDA 20-705/S-003

Pharmacia & UpJohn Company
Attention: James H. Chambers
Regulatory Manager, Regulatory Affairs
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. Chambers:

Please refer to your supplemental application (NDA) dated March 15, 1999, received March 16, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RESCRIPTOR® (delavirdine mesylate) Tablets, 200 mg.

We acknowledge receipt of your submissions dated:

March 16, 1999	July 2, 1999
May 17, 1999	July 9, 1999
May 28, 1999	

The supplemental application provides for a 200 mg tablet of RESCRIPTOR® (delavirdine mesylate).

We have completed our review of this supplemental application. The application is approved together with the negotiated changes in the WARNINGS and PRECAUTIONS sections regarding delavirdine-sildenafil and delavirdine-amprenavir interactions as indicated in the draft package insert dated July 9, 1999.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 16 copies and a .pdf file of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-705/S-003. Approval of this submission by FDA is not required before the labeling is used.

We remind you of your responsibility to comply with the requirements of 21 CFR §314.510 as indicated in the approval letter dated April 4, 1997.

We also 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, contact Ms. Grace N. Carmouze, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

Heidi M. Jolson, M.D., M.P.H.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV