DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-705/S-010

Pfizer, Incorporated
Pfizer Global Pharmaceuticals
Attention: Priso Epale
Manager, Regulatory Affairs
Worldwide Regulatory Affairs
and Quality Assurance
235 East 42nd Street,
New York, NY 10017

Dear Mr. Epale:

Please refer to your supplemental new drug application dated October 26, 2005, received October 27, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rescriptor® (delavirdine mesylate) Oral Tablets, 100 mg and 200 mg.

This "Changes Being Effected" supplemental new drug application includes PRECAUTIONS statements for drug interactions with fluticasone propionate and trazodone and information regarding Immune Reconstitution Syndrome.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

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 Victoria Tyson-Medlock, Regulatory Project Manager, at (301) 796-0827.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Final Printed Labeling

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

/s/

Jeffrey Murray

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