

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-705 / S-002

Trade Name: Rescriptor

Generic Name: (delavirdine)

Sponsor: Agouron Pharmaceuticals Inc.

Approval Date: October 23, 1998

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APPLICATION NUMBER:

20705 / S-002

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Not Approvable Letter(s)	
Final Printed Labeling	
Medical Review(s)	
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	

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20705 / S-002

APPROVAL LETTER

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

Dear Mr. Chambers:

Please refer to your supplemental new drug application dated April 22, 1998, received April 24, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RESCRIPTOR[®] (delavirdine mesylate) Tablets, 100 mg. The user fee goal date for this application is October 24, 1998.

We note that this supplement was submitted as a 'Special Supplement - Changes Being Effected' under 21 CFR §314.70(c).

This supplemental new drug application provides for an additional packaging site Pharmacia & Upjohn facility of 7000 Portage Road, Kalamazoo, Michigan. Your submission stated June 26, 1998 as the implementation date for these changes.

We have completed the review of this supplemental application and it is approved.

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, contact Debra Gump, R.Ph., Regulatory Management Officer, at (301) 827-2335.

Sincerely yours,

Stephen P. Miller, Ph.D.
Chemistry Team Leader for the
Division of Antiviral Drug Products, (HFD-530)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:
Archival NDA 20-705

HFD-530/Div. Files
HFD-530/D.Gump

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APPLICATION NUMBER:

20705 / S-002

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION HFD-530	2. NDA NUMBER 20,705
3. NAME AND ADDRESS OF APPLICANT (City and State) Pharmacia & Upjohn 7000 Portage Road Kalamazoo, MI 49001-0199		4. AF NUMBER	
		5. DOCUMENT(S) NUMBER(S) DATE(S) SCM-002 4/22/98	
6. NAME OF DRUG RESCRIPTOR		7. NONPROPRIETARY NAME Delavirdine Mesylate	
8. SUPPLEMENT(S) PROVIDES FOR: Change of packaging site for delavirdine mesylate tablets.		9. AMENDMENTS AND OTHER DATES	
10. PHARMACOLOGICAL CATEGORY Anti-viral	11. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	12. RELATED IND/NDA/DMF(S) DMF 2221, DMF 4266	
13. DOSAGE FORM(S) compressed tablets	14. POTENCY(IES): 100 mg, bottles of 360		
15. CHEMICAL NAME AND STRUCTURE Piperazine, 1-[3-[(1-methyl-ethyl)amino]-2-pyridinyl]-4-[[5-[(methylsulfonyl)amino]-1H-indol-2-yl]carbonyl]-, monomethanesulfonate		16. MEMORANDA	
17. COMMENTS <p>This supplement provides a new packaging site at Pharmacia & Upjohn facility of 7000 Portage Road, Kalamazoo, Michigan, in addition to a facility at _____.</p> <p>The facility at Michigan was inspected on April 9-26, 1996 and a certification of GMP compliance is provided with the supplement. An EER was forwarded through EES on June 25, 1998 with notification of the new packaging site. The compliance recommendation of "acceptable based on profile" was received on June 26, 1998.</p> <p>The applicant has provided a commitment statement that the first lot packaged at the Kalamazoo site will be placed on long term stability study and tested at least through one interval past the approved expiration dating period on the full testing schedule (3, 6, 9, 12, 18, 24 and then annually), with the results submitted through annual reports. The tests to be performed (potency, dissolution, water content and appearance) are equivalent to those in the yearly protocol.</p>			
18. CONCLUSIONS AND RECOMMENDATIONS All documentation that is recommended for a stand alone packaging change in the FDA SUPAC Letter of February 18, 1997 is provided. This supplement is therefore recommended for approval.			
19. REVIEWER			
NAME Zi-Qiang Gu, Ph.D.		SIGNATURE	DATE COMPLETED July 15, 1998
20. CONCURRENCE: HFD-530/SMiller			
DISTRIBUTION	<input checked="" type="checkbox"/> Orig. NDA	<input checked="" type="checkbox"/> Div. File	<input checked="" type="checkbox"/> HFD-830/CChen
	<input checked="" type="checkbox"/> HFD-530/SMiller	<input checked="" type="checkbox"/> HFD-530/DGump	<input checked="" type="checkbox"/> HFD-530/TNguyen
	<input checked="" type="checkbox"/> HFD-530/ZGu	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

NDA 20-705/S-002