

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-705 / S-008

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW # 1		DUE DATE -	1. ORGANIZATION HFD-530	2. NDA NUMBER 20-705	
3. NAME AND ADDRESS OF APPLICANT Agouron Pharmaceuticals, Inc. ATTN: Matthew E. Moran 10350 North Torrey Pines Road La Jolla, CA 92037			4. TYPE OF SUPPLEMENT PAS		
			5. DOCUMENT(S) NUMBERS SUBMITTED RECEIVED SE7-008 07/12/00 07/17/00		
6. NAME OF DRUG Rescriptor Tablets			7. NONPROPRIETARY NAME delavirdine mesylate tablets		
8. SUPPLEMENT(S) PROVIDES FOR: A number of revisions to the package insert and container labels to reflect clinical concerns and a change in corporate ownership.			9. AMENDMENTS AND OTHER DATES SLR-007 6/29/00 SLR-007 3/28/01 SE7-008 4/13/01		
10. PHARMACOLOGICAL CATEGORY Antiviral / Anti-HIV		11. HOW DISPENSED <input checked="" type="checkbox"/> R <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(s) SLR-005/6/7	
13. DOSAGE FORM(S) Tablets		14. POTENCY (CIES) 100 mg and 200 mg			
15. CHEMICAL NAME 1-{3-[(1-Methylethyl)amino]-2-pyridinyl}-4-[[5-(methylsulfonyl)amino]-1H-indol-2-yl]carbonyl}-piperazine, monomethanesulfonate			16. MEMORANDA		
17. COMMENTS This supplemental application provides for multiple modifications of the labeling to reflect a change in corporate ownership, changes in the clinical portions of the package insert, and addition of an Alert Box to the container labels. These changes are being reviewed as part of a supplement that provides for traditional approval of Rescriptor Tablets. There are no CMC concerns with any of the proposed changes to the package insert. After revisions to increase the prominence of the established name, the container labels are acceptable from the CMC perspective.					
18. CONCLUSIONS AND RECOMMENDATIONS From the chemistry, manufacturing and controls perspective, it is recommended that this supplement be approved.					
19. REVIEWER					
NAME Stephen P. Miller		SIGNATURE <i>{signed electronically}</i>		DATE COMPLETED 04/24/01	
20. CONCURRENCE: HFD-830/Bonnie Dunn <i>{signed electronically}</i>					
DISTRIBUTION	<input checked="" type="checkbox"/>	Original Jacket	<input checked="" type="checkbox"/>	ZGu	MO: LLewis
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				ONDC3 IO (CChen)	

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Chemistry Review

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/s/

Stephen Paul Miller

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CHEMIST

Container labels changed due to corporate ownership change and addition of Alert box.

Bonnie Dunn

5/1/01 07:12:51 AM

CHEMIST