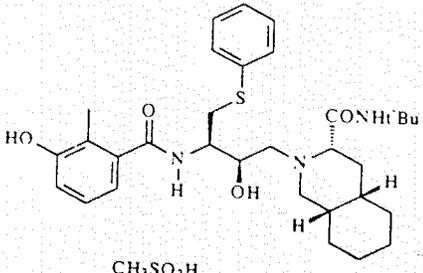
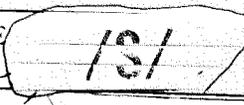


CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER for: 020778, S011

CHEMISTRY REVIEW(S)

BEST POSSIBLE COPY

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION HFD-530	2. NDA NUMBER 20-779
3. NAME AND ADDRESS OF APPLICANT (City and State) Agouron Pharmaceuticals, Inc. 10350 North Torrey Pines Road La Jolla, CA 92037-1022		4. AF NUMBER	
		5. SUPPLEMENT(S)	
		NUMBER(S) SE2-022	DATE(S) 1/26/99
6. NAME OF DRUG VIRACEPT [®] Tablets		7. NONPROPRIETARY NAME nelfinavir mesylate tablets	
8. SUPPLEMENT(S) PROVIDES FOR: BID dosing of Viracept (nelfinavir mesylate) tablets.		9. AMENDMENTS / REPORTS Amendment of 11/22/99	
10. PHARMACOLOGICAL CATEGORY Anti-HIV	11. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	12. RELATED IND/NDA/DMF(S)	
13. DOSAGE FORM(S) Tablets	14. POTENCY (IES) 250 mg		
15. CHEMICAL NAME AND STRUCTURE [3S-[2(2S*,3S*,3α,4aβ,8aβ)]-N-(1,1-dimethylethyl)decahydro-2-[2-hydroxy-3-[(3-hydroxy-2-methylbenzoyl)amino-4-(phenylthio)butyl]-3-isoquinolinecarboxamide], monomethanesulfonate (salt)		16. MEMORANDA	
 <p style="text-align: center;">CH₃SO₃H</p>			
17. COMMENTS None			
18. CONCLUSIONS AND RECOMMENDATIONS This Supplement provides for BID dosing of Viracept (nelfinavir mesylate) tablets. All CMC information has been previously submitted and approved. The package insert notes that the bottles now contain 300 tablets (as discussed during the review of 20-779/SCS-023). the tablets are film coated (reviewed in 20-779/SCF-027). the container should be kept tightly closed, and the tablets should be dispensed in the original container. In addition, the container label now contains the statements "Keep container tightly closed" and "Dispense in original container". This Supplement is therefore recommended for approval from a CMC perspective.			
19. REVIEWER			
NAME George Lunn, Ph.D.		SIGNATURE 	DATE COMPLETED 11/24/99
20. CONCURRENCE: HFD-530/SMiller			
DISTRIBUTION	<input checked="" type="checkbox"/> Original Jacket	<input checked="" type="checkbox"/> GLunn	<input checked="" type="checkbox"/> SLynche
	<input checked="" type="checkbox"/> Division File	<input checked="" type="checkbox"/> SMiller	<input checked="" type="checkbox"/> Med
	<input checked="" type="checkbox"/> HFD-830/CChen	<input checked="" type="checkbox"/> Micro	<input checked="" type="checkbox"/> PharmTox