

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-087 / S-004

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION HFD-530	2. NDA NUMBER 21-087
3. NAME AND ADDRESS OF APPLICANT (City and State) Hoffman-La Roche 340 Kingsland St. Nutley, NJ 08902		4. AF NUMBER	
		5. DOCUMENT(S) NUMBER(S) DATE(S) SCS-004 11/07/01	
6. NAME OF DRUG Tamiflu capsules	7. NONPROPRIETARY NAME Oseltamivir phosphate		
8. SUPPLEMENT(S) PROVIDES FOR: Extension of approved re-test date for the drug substance from 18 months to 24 months based on 24 months of real-time stability data.		9. AMENDMENTS AND OTHER (Reports, etc.) DATES	
10. PHARMACOLOGICAL CATEGORY Treatment of influenza A and B	11. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	12. RELATED IND/NDA/DMF(S) IND 53,093	
13. DOSAGE FORM(S) capsule	14. POTENCY(IES)	75 mg/ capsule	
15. CHEMICAL NAME AND STRUCTURE See current package insert		16. MEMORANDA	
17. COMMENTS <p>24 months of continuing real-time stability information was submitted on three batches of drug substance (80702944, 80703044, 80703144) included in the original NDA as primary stability batches. These batches were manufactured at _____ commercial scale by the commercial production _____ The stability samples were tested according to the approved protocol. The original retest date of 18 months was supported by 18 months of real-time data including the same 3 batches.</p> <p>The information in the current supplement demonstrates essentially no change in assay, specified degradants _____, unidentified impurities, total impurities, appearance or water content at either _____ up to 24 months. Each of these parameters was well within the approved acceptance limits for each test.</p>			
18. CONCLUSIONS AND RECOMMENDATIONS The information provided demonstrates that there is no change in the drug substance from 18 months to 24 months. It is, therefore, recommended that this supplemental application for extension of drug substance re-test to 24 months be approved.			
19. REVIEWER			
NAME Dan Boring	SIGNATURE /see electronic signature/	DATE COMPLETED 02/28/01	
20. CONCURRENCE: HFD-830/SMiller /see electronic signature/			

/s/

Dan Boring
3/5/01 11:25:14 AM
CHEMIST

Stephen Paul Miller
3/6/01 09:00:39 AM
CHEMIST