

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-087 / S-007

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW		DUE DATE 07/16/01	1. ORGANIZATION HFD-530	2. NDA NUMBER 21-087	
3. NAME AND ADDRESS OF APPLICANT Hoffman-La Roche 340 Kingsland St. Nutley, NJ 08902			4. TYPE OF SUPPLEMENT PAS		
			5. DOCUMENT(S)		
6. NAME OF DRUG Tamiflu capsules			NUMBERS SCE-007	DATED 03/13/01	RECEIVED 03/14/01
			7. NONPROPRIETARY NAME Oseltamivir phosphate		
8. SUPPLEMENT PROVIDES FOR: Extension of approved expiration dating from 18 months to 24 months based on 24 months of real-time stability data for capsules for physician sampling.				9. AMENDMENTS/DATES None	
10. PHARMACOLOGICAL CATEGORY Treatment of influenza A and B		11. HOW DISPENSED <input checked="" type="checkbox"/> R <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(s) IND 53,093	
13. DOSAGE FORM(S) Capsules		14. POTENCY (CIES) 75 mg/ capsule			
15. CHEMICAL NAME AND STRUCTURE See Package insert				16. MEMORANDA None	
17. COMMENTS					
18. CONCLUSIONS AND RECOMMENDATIONS The information provided demonstrates that there is little change in the drug product for up to 24 months packaged in the _____ It is recommended that this supplemental application for extension of expiration to 24 months be approved.					
19. REVIEWER					
NAME Dan Boring, Ph.D.		SIGNATURE <i>[signed electronically in DFS]</i>		DATE OF DRAFT REVIEW 07/11/01	
20. CONCURRENCE: HFD-530/SMiller <i>[signed electronically in DFS]</i>					
DFS CC LIST	<input type="checkbox"/> L	<input type="checkbox"/> DBoring	<input type="checkbox"/> L	<input type="checkbox"/> MO/TWu	<input type="checkbox"/> PharmTox
L = Action Letter	<input type="checkbox"/> RL	<input type="checkbox"/> SMiller	<input type="checkbox"/> RL	<input type="checkbox"/> PM/GCarmouze	<input type="checkbox"/> Micro
R = Review	<input type="checkbox"/> RL	<input type="checkbox"/> ONDC3 IO (CChen)	<input type="checkbox"/>	<input type="checkbox"/> Biopharm	<input type="checkbox"/>

REVIEW NOTES:

The following drug product material was packaged each into

Batches tested

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

/s/

Dan Boring
9/6/01 04:43:00 PM
CHEMIST

Stephen Paul Miller
9/14/01 11:27:04 AM
CHEMIST