

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-087 / S-011

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA		1. ORGANIZATION	2. NDA NUMBER
CHEMIST'S REVIEW		HFD-530	21-087
3. NAME AND ADDRESS OF APPLICANT (City and State)		4. AF NUMBER	
Hoffman-La Roche 340 Kingsland St. Nutley, NJ 08902		5. DOCUMENT(S)	
		NUMBER(S)	DATE(S)
		SCS-011	11/28/01
6. NAME OF DRUG		7. NONPROPRIETARY NAME	
Tamiflu capsules		Oseltamivir phosphate capsules	
8. SUPPLEMENT(S) PROVIDES FOR:		9. AMENDMENTS AND OTHER	
Extension of approved re-test date for the drug substance from 24 months to 36 months based on 36 months of real-time stability data tested according to the approved stability protocol.		<i>(Reports, etc.)</i> DATES	
10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)	
Treatment of influenza A and B	<input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	IND 53,093, NDA 21-246	
13. DOSAGE FORM(S) capsule		14. POTENCY(IES)	75 mg/ capsule
15. CHEMICAL NAME AND STRUCTURE		16. MEMORANDA	
See current package insert			
17. COMMENTS			
<div style="border-left: 1px solid black; border-right: 1px solid black; border-bottom: 1px solid black; width: 100%; height: 100%;"></div>			
18. CONCLUSIONS AND RECOMMENDATIONS			
The information provided demonstrates that there is no change in the drug substance from 24 months to 36 months. It is, therefore, recommended that this supplemental application for extension of drug substance re-test to 36 months be approved.			
19. REVIEWER			
NAME	SIGNATURE	DATE COMPLETED	
Dan Boring	<i>/see electronic signature/</i>	03/22/02	
20. CONCURRENCE: HFD-530/DNDC-830/SMiller <i>/see electronic signature/</i>			

**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
3/25/02 02:41:09 PM
CHEMIST

Stephen Paul Miller
3/28/02 02:48:08 PM
CHEMIST