CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-087 / S-003

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)*	4. AF NUMBER
Hoffman-La Roche 340 Kingsland St. Nutley, NJ 08902	5. DOCUMENT(S) NUMBER(S) DATE(S) SCE-003 10/4/00

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Tamiflu capsules	Oseltamivir phosphate

8. SUPPLEMENT(S) PROVIDES FOR:	9. AMENDMENTS AND OTHER *(Reports, etc.)* DATES
Extension of approved expiration date from 18 months to 24 months based on 24 months of real-time stability data for blisters and bottles.	

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)
Treatment of influenza A and B	|X| Rx | | OTC	IND 53,093

13. DOSAGE FORM(S) capsule	14. POTENCY(IES) 75 mg/ capsule

15. CHEMICAL NAME AND STRUCTURE	16. MEMORANDA
See current package insert	

17. COMMENTS

[redacted]

18. CONCLUSIONS AND RECOMMENDATIONS

The information provided demonstrates that there is little change in the drug product from 12 months to 24 months. It is, therefore, recommended that this supplemental application for extension of expiration to 24 months be approved.

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Dan Boring		11/2/00

20. CONCURRENCE: HFD-830/SMiller

DISTRIBUTION	X	Original Jacket	X	DBoring	X	CChen
	X	Division File			X	GCarmouze

/s/

Dan Boring
11/2/00 12:01:00 PM
CHEMIST

Stephen Paul Miller
11/2/00 04:33:47 PM
CHEMIST
I concur