CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-246 / S-002

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW	1. ORGANIZATION HFD-530	2. NDA NUMBER 21-246

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) SCS-002	DATE(S) 03/05/01

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Tamiflu suspension	Oseltamivir phosphate for oral suspension

8. SUPPLEMENT(S) PROVIDES FOR:	9. AMENDMENTS AND OTHER *(Reports, etc.)* DATES
Deletion of the Uniformity of dosage units by content uniformity release testing of each batch.	

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)
Treatment of influenza A and B	|X| Rx | | OTC	IND 53,093, NDA 21,087

13. DOSAGE FORM(S) oral suspension	14. POTENCY(IES)	12 mg/ mL

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

17. COMMENTS

At the end of the review cycle for NDA 21-246, Roche made several changes in their manufacturing process to address concerns about the homogeneity of dosage units across a manufacturing run. The process improvements were demonstrated on pilot scale production batches and seemed to correct the homogeneity problems. However, to be certain that the process improvements would continue to be effective during full production campaigns, it was recommended that Roche continue with homogeneity testing and submit the results of homogeneity testing on all launch and validation batches.

The results of the homogeneity testing on the launch and validation batches (9 batches in total) were consistent and satisfactory. Roche has manufactured additional full scale commercial batches which are also satisfactory

There doesn't appear to be any continuing need to test for Uniformity of Dosage Units.

18. CONCLUSIONS AND RECOMMENDATIONS

The information provided demonstrates that there is no continuing need to conduct batch uniformity testing. It is recommended that this supplemental application for deletion of the uniformity of dosage units release testing be approved.

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Dan Boring	*/see electronic signature/*	**06/27/01**

20. CONCURRENCE: HFD-830/SMiller */see electronic signature/*

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
7/9/01 05:13:20 PM
CHEMIST

Stephen Paul Miller
8/29/01 05:17:29 PM
CHEMIST