CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-246 / S-006

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-006	DATE(S) 09/04/01

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

8. SUPPLEMENT(S) PROVIDES FOR:	9. AMENDMENTS AND DATES
Addition of 25-ml bottle size for more efficient medication use.	SCS-006/BC 10/18/01

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

Tamiflu suspension is indicated for the treatment of influenza in pediatric and adult patients with dosing based on the weight of the patient. Roche had marketed a single bottle size (75-ml of suspension in a 100-ml bottle) for product launch with enough medication to cover an adult treatment regimen. However, the primary population for this product is children, therefore DAVDP had recommended that a more efficient package size be developed so that less medication would be discarded during pediatric use.

18. CONCLUSIONS AND RECOMMENDATIONS

The proposed 60-ml bottle containing 25-ml of suspension appears comparable in every way to the existing 100-ml bottle containing 75-ml of suspension. It is recommended that the 60-ml bottle presentation be approved in addition to the existing 100-ml bottle.

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Dan Boring	*/see electronic signature/*	**02/25/02**

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

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/s/

Dan Boring
2/26/02 11:22:07 AM
CHEMIST

Stephen Paul Miller
2/28/02 03:50:36 PM
CHEMIST