

# CENTER FOR DRUG EVALUATION AND RESEARCH

## *APPLICATION NUMBER:*

**21-087 / S-005**

**21-087 / S-006**

**21-246 / S-001**

## **CHEMISTRY REVIEW(S)**

<b>SUPPLEMENTAL NDA CHEMIST'S REVIEW</b>		<b>1. ORGANIZATION</b> HFD-530	<b>2. NDA NUMBER</b> 21-087
<b>3. NAME AND ADDRESS OF APPLICANT (City and State)</b> Hoffman-La Roche 340 Kingsland St. Nutley, NJ 08902		<b>4. AF NUMBER</b>	
		<b>5. DOCUMENT(S)</b>	
		<b>NUMBER(S)</b> SLR-005	<b>DATE(S)</b> 12/08/2000
<b>6. NAME OF DRUG</b> Tamiflu capsules	<b>7. NONPROPRIETARY NAME</b> Oseltamivir phosphate		
<b>8. SUPPLEMENT(S) PROVIDES FOR:</b> Removal of ethanol and purified water from the Description section of the package insert		<b>9. AMENDMENTS AND OTHER (Reports, etc.) DATES</b>	
<b>10. PHARMACOLOGICAL CATEGORY</b> Treatment of influenza A and B	<b>11. HOW DISPENSED</b> <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	<b>12. RELATED IND/NDA/DMF(S)</b> IND 53,093	
<b>13. DOSAGE FORM(S)</b> capsule	<b>14. POTENCY(IES)</b>	75 mg/ capsule	
<b>15. CHEMICAL NAME AND STRUCTURE</b> See current package insert		<b>16. MEMORANDA</b>	
<b>17. COMMENTS</b> This CBE-0 supplement provides for Roche to remove ethanol and purified water from the list of product constituents found in the Description section of the package insert.			
<b>18. CONCLUSIONS AND RECOMMENDATIONS</b> There are no chemistry, manufacturing and controls issues and it is recommended that this supplement be approved to allow the removal of ethanol and purified water from the list of constituents in the package insert.			
<b>19. REVIEWER</b>			
<b>NAME</b> Dan Boring	<b>SIGNATURE</b> /see electronic signature/		<b>DATE COMPLETED</b> 04/13/01
<b>20. CONCURRENCE:</b> HFD-830/SMiller /see electronic signature/			

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/s/  
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Dan Boring  
5/1/01 11:19:47 AM  
CHEMIST

Removal of ethanol and water from description

Stephen Paul Miller  
5/8/01 08:24:48 AM  
CHEMIST