

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**21-087 / S-010**

**21-246 / S-007**

**APPROVAL LETTER**



NDA 21-087/S-010  
NDA 21-246/S-007

Hoffman-La Roche Inc.  
Attention: Ms. Duane L. Voss  
Program Director, Drug Regulatory Affairs  
340 Kingsland Street  
Nutley, NJ 07110-1199

Dear Ms. Voss:

Attached is the correct version of the Final Printed labeling-Changes Being Effected. Please note no additional changes were made from the previous approval letter. This letter will supersede the approval letter sent April 9, 2002.

Please refer to your supplemental new drug applications dated September 11, 2001, received September 13 and September 14, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tamiflu<sup>®</sup> (oseltamivir phosphate) capsules and oral suspension

We acknowledge receipt of your submissions dated September 11, 2001.

These "Changes Being Effected" supplemental new drug applications provide for a smaller package size (60ml bottles containing 25ml of suspension after constitution) of Tamiflu<sup>®</sup> for oral suspension.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted and patient package insert submitted September 11, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Vasavi Reddy, R.Ph., Regulatory Project Manager, at 301-827-2335.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, M.D.  
Director  
Division of Antiviral Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

**Attachment:**

Clean version of Package Insert and Patient Package Insert

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Debra Birnkrant  
4/26/02 08:53:24 AM  
NDA 21-087, 21-246