



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-025

Hoffmann-La Roche Inc.
Attention: Duane L. Voss
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Voss:

Please refer to your supplemental new drug application dated May 23, 2005, received May 24, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tamiflu® (oseltamivir phosphate) Capsules.

We acknowledge receipt of your submissions dated:

September 6, 2005	October 14, 2005
September 7, 2005	October 20, 2005
October 6, 2005	

This supplemental new drug application provides for a new bottle label for the previously approved 10-count bottle of Tamiflu capsules. This label is for use for stockpiling by state government, state government agencies, groups acting on behalf of state governments, and Federal entities. There are four versions of the container label: with and without tear-off strips, and with the country of origin and without the country of origin, for use on bottles of capsules sourced using a U.S.-only supply chain. In addition, these bottles will be distributed with the following statement:

At the present time, drugs held in non-Federal stockpiles are not eligible for shelf life extension by the Shelf Life Extension Program (SLEP). In addition it may not be feasible to use SLEP to extend the shelf life of drugs held in small Federal stockpiles or in Federal stockpiles that have not been stored under well defined conditions. For further details please contact Donna Porter at the FDA (e-mail: donna.porter@fda.hhs.gov).

We further acknowledge your agreement to provide information that would support use of stockpiled Tamiflu capsules in pediatric patients by using them to prepare an extemporaneous formulation. We believe that it is critical to develop dosing instructions that could be used by a parent or guardian using commonly available materials and have these instructions available prior to an emergency.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text, submitted October 21, 2005.

The final printed labeling (FPL) must be identical to the enclosed labeling.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-087/S-025**". Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jeff D. O'Neill, Regulatory Health Project Manager, at (301) 796-0777.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Immediate carton labels

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

/s/

Debra Birnkrant
10/27/2005 11:37:39 AM
NDA 21-087