DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-041
NDA 21-246/S-028

Hoffman-La Roche Inc.
Attn: Ellen Carey, Senior Program Manager
Drug Regulatory Affairs
340 Kingsland Street
Nutley, New Jersey 07110

Dear Ms. Carey:

Please refer to your supplemental new drug applications dated March 29, 2007, received March 30, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tamiflu® (oseltamivir phosphate) Oral Suspension and Capsules.

We acknowledge receipt of your submissions dated July 20, 2007, August 3, 2007, August 8, 2007, September 5, 2007, September 28, 2007, and October 2, 2007.

Specifically, these supplemental new drug applications:

- provide language in the **MICROBIOLOGY: Mechanism of Action** section of the package insert to update information about activity of oseltamivir carboxylate.

- provide language in the **PRECAUTIONS: Information for Patients** section of the package insert to include a paragraph on the amount of sorbitol in each 13 g bottle and 75 mg twice daily dose of Tamiflu® for Oral Suspension.

- provide language in the **PRECAUTIONS: Carcinogenesis, Mutagenesis, and Impairment of Fertility** section of the package insert to include 2 year carcinogenicity data in mice and rats, from completed Research Study Reports.

- provide language in the **Who should not take Tamiflu** section of the patient package insert to include the precaution “family history of fructose intolerance”.

We completed our review of these supplemental applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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 these submissions "**FPL for approved supplement NDA 21-087/S-041 and NDA 21-246/S-028.”** Approval of these submissions 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 the NDAs and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

Enclosures: Package Insert, 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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Jeffrey Murray
10/5/2007 12:39:33 PM