DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-040
NDA 21-246/S-027

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 8, 2007, received March 9, 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 April 2, 2007, June 4, 2007, June 21, 2007, and June 29, 2007.

Specifically, these supplemental new drug applications provide for:

- manufacture, packaging and testing of the 30 mg and 45 mg capsules at the sites listed in the supplemental application;
- addition of the 30 mg and 45 mg capsules to the **DESCRIPTION** section of the package insert;
- updates to tables 5 and 6 in the **DOSAGE and ADMINISTRATION** section of the package insert to include dosing instructions for the 30 mg and 45 mg capsules;
- addition of descriptions of the 30 mg and 45 mg capsules in the **HOW SUPPLIED** section of the package insert; and
- carton and container labeling for 30 mg and 45 mg foil trade packages, Department of Defense stockpiles, state stockpiles, and Strategic National Stockpiles.

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-040 and NDA 21-246/S-027.**" 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 this NDA 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, and Carton and Container Labels

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/s/

Debra Birnkrant
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NDA 21-246, 21-087,