DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-033
NDA 21-246/S-021

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 June 12, 2006, received June 14, 2006, 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 August 11, 2006, September 7, 2006, October 3, 2006, October 12, 2006, October 13, 2006, October 26, 2006, October 31, 2006, November 1, 2006, and November 9, 2006.

Specifically, these supplemental new drug applications:

- provide language in the **PRECAUTIONS** section of the package insert and in the section of the patient package insert, **What are the possible side effects of Tamiflu®?** regarding information that patients with influenza should be closely monitored for signs of abnormal behavior while taking Tamiflu®;

- provide language in the **DRUG INTERACTIONS** section of the package insert and patient package insert regarding concurrent use of Tamiflu with live attenuated influenza vaccine intranasal;

- provide instructions for pharmacists for the preparation of a suspension using the contents of Tamiflu® Capsules in an emergency setting, when the commercially manufactured oral suspension is not available; and

- provide clarification regarding the volume declaration for Tamiflu® Oral Suspension in the **HOW SUPPLIED** section of the package insert.

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-033 and NDA 21-246/S-021.”** 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

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
11/13/2006 03:23:22 PM
NDA 21-087, 21-246