DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-042
NDA 21-246/S-030

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 July 13, 2007, received July 17, 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 December 6, 2007, December 18, 2007, December 19, 2007, December 20, 2007, January 4, 2008, January 11, 2008, and January 16, 2008.

Specifically, these supplemental new drug applications:

- provide language in the MICROBIOLOGY: Resistance section
- provide language in the CLINICAL PHARMACOLOGY: Special Populations: Hepatic Impairment section
- provide language in the PRECAUTIONS: Hepatic Impairment section
- provide language in the PRECAUTIONS: Neuropsychiatric Events section
- provide language in the DOSAGE AND ADMINISTRATION: Special Dosage Instructions: Hepatic Impairment section
- provide language in the PRECAUTIONS: Drug Interactions section regarding lack of observed interactions during co-administration of oseltamivir with amoxicillin, acetaminophen, cimetidine or with antacids.
- provide language in the ADVERSE REACTIONS: Observed During Clinical Practice section with gastrointestinal events
- provide language in the What are the possible side effects of Tamiflu section of the Patient Package Insert regarding neuropsychiatric events.

We have 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.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the patient package insert) and/or submitted labeling (package insert submitted

January 16, 2008, patient package insert submitted January 11, 2008). Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-087 and NDA 21-246".

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

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
1/17/2008 12:16:15 PM
NDA 21-246, 21-087