DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-087/S-029
NDA 21-246/S-019

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 applications dated September 26, 2005, received September 28, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TAMIFLU® (oseltamivir phosphate) Capsules, 75 mg, and TAMIFLU® (oseltamivir phosphate) Suspension, 60 mg per 5 mL.

We acknowledge receipt of your submission dated October 21, 2005.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for changes in the HPLC-MS test method for impurity (b) (4) in drug substance manufactured at Roche Basel and Roche Carolina.

We completed our review of these supplemental new drug applications. These supplements are approved.

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

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

Sincerely,

{See appended electronic signature page}

Stephen P. Miller, Ph.D.
Chemistry Pharmaceutical Assessment Lead for the
Division of Antiviral Products
DPA-2, Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

/s/

Stephen Paul Miller
12/1/2005 02:06:21 PM
NDAs 21-087/S-029 and 21-246/S-019 are approved