DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-087/S-028
NDA 21-246/S-018

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 22, 2005, received September 23, 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.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for changes in the (b) (4) operations for oseltamivir phosphate API at 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 Team Leader for the
Division of Antiviral Drug Products, (HFD-530)
DNDC III, Office of New Drug Chemistry
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
10/14/2005 05:14:40 PM
NDAs 21-087/S-028 adn 21-246/S-018 are approved