DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-087/S-020
NDA 21-246/S-013

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 14, 2004, received September 15, 2004, 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" supplemental new drug applications provide for an additional facility, Roche Colorado, for the manufacture of the starting material (b) (4).

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) 827-2335.

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

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/s/

Stephen Paul Miller
10/19/04 03:17:36 PM
NDAs 21-087/S-020 and 21-246/S-013 are approved