DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-087/S-019
NDA 21-246/S-012

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 March 1, 2004, received March 2, 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 supplemental new drug applications provide for an alternate manufacturing and testing site, Roche Carolina Inc., for the final step in the manufacture of oseltamavir phosphate.

We completed our review of these supplemental new drug applications. These supplements are approved. The data provided support a (b) (4) month retest date for drug substance manufactured by Roche Carolina (as approved for drug substance manufactured by Roche Basel in Supplement 21-087/S-018).

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, 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
8/12/04 05:24:05 PM
NDAs 21-087/S-019 and 21-246/S-012 are approved