



NDA 21-087/S-021
NDA 21-246/S-014

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 November 19, 2004, received November 22, 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 changes in the test methods for impurity (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, 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
1/18/05 07:53:05 PM
NDAs 21-087/S-021 and 21-246/S-014 are approved