DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-035
NDA 21-246/S-022

Hoffmann-La Roche, Inc.
Attention: Duane L. Voss
Program Director
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Voss:

Please refer to your supplemental new drug applications dated August 3, 2006, received August 4, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

Application	Product	Supplement
NDA 21-087	Tamiflu® (oseltamivir phosphate) Capsules	S-035
NDA 21-246	Tamiflu® (oseltamivir phosphate) for Oral Suspension	S-022

These "Changes Being Effected" supplemental new drug applications provide for a scale up to the manufacturing process of oseltamivir phosphate and an improvement to the final (b) (4) at Roche Carolina, Inc. (RCI).

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 Valerie Jimenez, MS, Senior Regulatory Project Manager, at (301) 796-1345.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
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/

Hasmukh Patel

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