DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-039
NDA 21-246/S-026

Hoffmann-La Roche, Inc.
Attention: Arun Chalgeri, Ph.D.
Program Manager, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110

Dear Dr. Chalgeri:

Please refer to your supplemental new drug applications dated December 18, 2006, received December 19, 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-039
NDA 21-246	Tamiflu® (oseltamivir phosphate) for Oral Suspension	S-026

These "Changes Being Effected in 30 days" supplemental applications propose an alternate (b) (4) in the manufacture of oseltamivir phosphate, using (b) (4), to further increase throughput at the Roche Basel site.

We have 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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