DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-043

Hoffmann-La Roche, Inc.
Attention: Duane Voss
Program Manager, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110

Dear Ms. Voss:

Please refer to your supplemental new drug application dated November 2, 2007, received November 5, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tamiflu® (oseltamivir phosphate) Capsules.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate manufacturing site for the drug product, (b) (4)

We completed our review of this supplemental new drug application. This supplement is 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 Althea Cuff, Regulatory Health Project Manager, at (301) 796-4061.

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

5/5/2008 01:37:37 PM