DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-246/S-032

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

Dear Ms. Voss:

Please refer to your supplemental new drug application dated October 22, 2008, received October 23, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tamiflu® (oseltamir phosphate) Oral Suspension.

This "Prior Approval" supplemental new drug application provides for a reduction in the stability testing frequency for the drug product.

We completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Althea Cuff, Regulatory Project Manager, at (301)796-4061.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

Hasmukh Patel

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