DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-031
NDA 21-246/S-020

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

Dear Ms. Voss:

Please refer to your supplemental new drug applications dated April 3, 2006, received April 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-031
NDA 21-246	Tamiflu® (oseltamivir phosphate) Oral Suspension	S-020

We acknowledge receipt of your submission dated April 7, 2006.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for a scale up to the synthesis of oseltamivir phosphate API, with improvements to the final (b) (4).

We completed our review of these supplemental new drug applications, as amended. 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, 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/

Eric Duffy
6/23/2006 03:00:30 PM