



NDA 21-087/S-037
NDA 21-246/S-024

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 September 13, 2006, received September 14, 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-037
NDA 21-246	Tamiflu® (oseltamivir phosphate) for Oral Suspension	S-024

These “Changes Being Effected” supplemental new drug applications propose two additional alternate facilities, (b) (4) for the manufacture of the (b) (4), which is the (b) (4) in the production of oseltamivir phosphate API.

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

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/s/

Hasmukh Patel

3/12/2007 01:40:35 PM