



Hoffmann-La Roche Inc.
Attention: Duane L. Voss
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Voss:

Please refer to your supplemental new drug application dated March 31, 2005, received April 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TAMIFLU[®] (oseltamivir phosphate) Capsules, 75 mg.

This "Changes Being Effected" supplemental new drug application provides for a new packaging configuration (10-count, unit-of-use bottle), a new packaging site, a new container label, and a prophylaxis sticker.

We completed our review of this supplemental new drug application. This supplement is approved, effective on the date of this letter, for use as recommended in the final printed labeling immediate container and prophylaxis sticker submitted with the supplement.

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 Jeff O'Neill, ACRN, Regulatory Health Project Manager, at (301) 827-2362.

Sincerely,

{See appended electronic signature page}

Stephen P. Miller, Ph.D.
Chemistry Team Leader for the
Division of Antiviral Drug Products, (HFD-530)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Attachments: Immediate container label and prophylaxis sticker

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Stephen Paul Miller
4/20/05 12:14:16 PM
NDA 21-087/ S-023 is approved