DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-087/S-027

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 applications dated September 9, 2005, received September 12, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TAMIFLU® (oseltamivir phosphate) Capsules, 75 mg.

We acknowledge receipt of your submissions dated September 27, 2005 and October 7, 2005.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate manufacturing and release site for Tamiflu capsules at (b) (4). The data provided support a 60-month expiration dating period, as approved in NDA 21-087/S-017 for capsules manufactured at Roche Basel.

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, please call Jeff O'Neill, ACRN, Regulatory Project Manager, at (301) 796-0777.

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

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/s/

Stephen Paul Miller
10/14/2005 04:35:49 PM
NDA 21-087 / S-027 is approved