DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-087/S-017

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 February 12, 2004, received February 13, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TAMIFLU® (oseltamivir phosphate) Capsules, 75 mg.

This supplemental new drug application provides for extension of expiration dating from 48 months to 60 months based on 60 months of real-time stability information on NDA pilot scale batches packaged in blisters, bottles and pouches.

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, call Jeff O'Neill, ACRN, Regulatory Project Manager, at (301) 827-2335.

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
4/26/04 03:23:54 PM
NDA 21-087 / S-017 is approved