DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-046

Hoffmann-La Roche Inc.
Attention: Duane Voss
Program Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Voss:

Please refer to your supplemental new drug application dated June 2, 2008, received June 3, 2008, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for TAMIFLU (oseltamivir phosphate) capsules.

This supplemental new drug application proposes to use the 75 mg capsules packaged in the currently approved blister card presentation, intended for corporate stockpiling, with the following labeling modifications made to the carton:

- Layout rearranged and red and blue corporate striping removed
- Distributor's name changed from Roche Laboratories, Inc. to (b) (4)
- "For Corporate Stockpile Only" and "Not for Individual Sale" statements added to carton
- New NDC number assigned

We completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Elizabeth Thompson, M.S., Regulatory Project Manager, at (301) 796-0824.

Sincerely,

{See appended electronic signature page}

Eric Duffy, Ph.D.
Director
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

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