



NDA 21-087/S-026

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

Dear Ms. Voss:

Please refer to your new drug application (NDA) dated June 27, 2005, received June 28, 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 submission dated July 26, 2005.

This "Changes Being Effected" supplemental new drug application provides for a new bottle label and prophylaxis stickers for the unit-of-use bottles of 10 count specific for stockpiling by the Department of Defense.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling submitted in your correspondence dated July 26, 2005.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jeffrey O'Neill, Regulatory Project Manager, at 301-827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Food and Drug Administration

Enclosure: 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/

Jeffrey Murray
8/16/2005 01:33:28 PM