



NDA 21-087/S-015

Hoffman-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 November 1, 2002, received November 4, 2002, 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 36 months to 48 months based on 48 months of real-time stability information on NDA pilot scale batches packaged in blisters bottles and pouches.

We have completed the review of this supplemental application, and it 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 Sean J. Belouin, R.Ph., 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
2/28/03 05:46:20 PM
NDA 21-087 S-015 is approved