DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-087/S-014
NDA 21-246/S-008

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 October 11, 2002, received October 15, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TAMIFLU® (oseltamivir phosphate) Capsules, 75 mg, and TAMIFLU® (oseltamivir phosphate) Suspension, 60 mg per 5 mL.

These supplemental new drug applications provide for extension of the approved retest period for the drug substance from (b) (4) months based on 4 years of real-time stability data from the three NDA batches (pilot scale).

We have completed the review of these supplemental applications, and they are 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
2/14/03 11:26:42 AM
NDA 21-087 S-014 and 21-246 S-008 are approved