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APPLICATION NUMBER:

21-087 / S-011

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-087/S-011

Hoffmann-La Roche Inc.
Attention: Duane Voss
340 Kingsland St.
Nutley, NJ 08902

Dear Ms. Voss:

Please refer to your supplemental new drug application dated November 27, 2001, received November 28, 2001, 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 the approved retest date for oseltamivir phosphate drug substance from 24 months to 36 months.

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 Vasavi Reddy, R.Ph., Regulatory Project Manager, at (301) 827-2335.

Sincerely yours,

{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
3/28/02 04:53:06 PM
21-087 S-011 is approved