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APPLICATION NUMBER:

21-087 / S-007

APPROVAL LETTER



NDA 21-087/S-007

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 March 13, 2001, received March 14, 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 the extension of approved expiration dating from 18 months to 24 months for capsules _____ for physician sampling.

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 Grace N. Carmouze, 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
7/13/01 01:31:26 PM
21-087 S-007 is approved