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APPLICATION NUMBER:

21-087 / S-003

APPROVAL LETTER



NDA 21-087/S-003

Hoffmann-La Roche Inc.
Attention: Duane L. Voss
Program Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Voss:

Please refer to your supplemental new drug application dated October 3, 2000, received October 4, 2000, 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 an extension of approved expiration date from 18 months to 24 months based on 24 months of real-time stability data for blisters and bottles.

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,

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

/s/

Stephen Paul Miller
11/9/00 04:53:03 PM