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***APPLICATION NUMBER:***

**21-087 / S-004**

**APPROVAL LETTER**



NDA 21-087/S-004

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 November 6, 2000, received November 7, 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 re-test date for the drug substance from 18 months to 24 months based on 24 months of real-time stability data.

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) 827-2330.

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

/s/

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Stephen Paul Miller  
3/6/01 08:43:37 AM