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***APPLICATION NUMBER:***

**21-087 / S-001**

**APPROVAL LETTER**

NDA 21-087



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

NDA 21-087/S-001

Hoffman-La Roche  
Attention: Duane L. Voss  
Program Director  
Drug Regulatory Affairs  
340 Kingsland St.  
Nutley, NJ 08902

OCT 31 2000

Dear Ms. Voss:

Please refer to your supplemental new drug application dated May 1, 2000, received May 2, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tamiflu™ (oseltamivir phosphate) Capsules, 75 mg.

This "Changes Being Effectuated" supplemental new drug application provides for an alternate facility,

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