

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**21-087 / S-007**

**ADMINISTRATIVE DOCUMENTS**  
**AND**  
**CORRESPONDENCE**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-087/S-007

**PRIOR APPROVAL SUPPLEMENT**

Hoffmann-La Roche Inc.  
Attention: Duane L. Voss  
Program Director  
340 Kingsland Street  
Nutley, New Jersey 07110-1199

Dear Ms. Voss,

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Tamiflu™ (oseltamivir phosphate) Capsules

NDA Number: 21-087

Supplement number: S-007

Date of supplement: March 13, 2001

Date of receipt: March 14, 2001

This supplemental application proposes the following change: extension of expiration date for capsules packaged in \_\_\_\_\_ from 18 months to 24 months.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on May 16, 2001 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

Courier/Overnight Mail:  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Antiviral Drug Products, HFD-530  
Attention: Document Room  
9201 Corporate Boulevard  
Rockville, Maryland 20850

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If you have any question, please call Ms. Grace Carmouze, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

Anthony W. DeCicco, R. Ph.  
Chief, Project Management Staff  
Division of Antiviral Drug Products, HFD-530  
Center for Drug Evaluation and Research  
Food and Drug Administration

/s/

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Tony DeCicco  
3/28/01 10:33:52 AM