

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-087 / S-012

ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-012

PRIOR APPROVAL SUPPLEMENT

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

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-012
Date of supplement:	January 4, 2002
Date of receipt:	January 7, 2002

This supplemental application proposes for a further extension of the approved expiration date for Tamiflu® (oseltamivir phosphate) capsules, from 24 months to 36 months for capsules packaged in

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 March 6, 2002 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:

Center for Drug Evaluation and Research
Division of Antiviral Drug Products, HFD-530
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

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

If you have any questions, call Grace N. Carmouze, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

Anthony W. DeCicco, R.Ph.
Chief, Project Management Staff
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Tony DeCicco
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