

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER for: 021087

CHEMISTRY REVIEW(S)

DIVISION OF ANTIVIRAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA#: 21-087

CHEMISTRY REVIEW #: 1

DATE REVIEWED: 10/4/99

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
CMC Pre-Submission	3/8/99	3/9/99	3/17/99
Original NDA	4/29/99	4/30/99	5/3/99
Amendment, BC	8/17/99	8/18/99	8/20/99
Amendment, BC	9/7/99	9/10/99	9/12/99
Amendment, BC	10/8/99	10/12/99	10/13/99
Amendment, BC	10/13/99	10/14/99	10/15/99

NAME & ADDRESS OF SPONSOR: Hoffman-LaRoche, Inc
340 Kingsland St
Nutley, NJ 07110

DRUG PRODUCT NAMES:

Proprietary	Tamiflu™
Nonproprietary	oseltamivir phosphate capsules
Code Name	

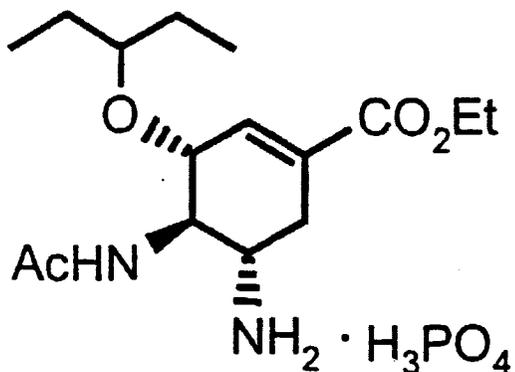
PHARMACOLOGICAL CATEGORY: Viral neuraminidase inhibitor

INDICATION: Treatment of influenza's A and B

DOSAGE FORM/STRENGTH: Capsule/75 mg

ROUTE OF ADMINISTRATION: Oral

CHEMICAL NAME/STRUCTURAL FORMULA:



(3R,4R,5S)-4-Acetylamino-5-amino-3-(1-ethylpropoxy)-1-cyclohexene-1-carboxylic acid, ethyl ester, phosphate (1:1)

Mol. Form. - C₁₆H₂₈N₂O₄

SUPPORTING DOCUMENTS:

IND: _____

DMF's _____

RELATED DOCUMENTS:

The CDER Labeling and Nomenclature Committee found the proposed proprietary name TAMIFLU to be acceptable as noted by Attachment.

CONCLUSIONS & RECOMMENDATIONS:

This application, as amended, is in conformance with section 505(b) of the Food, Drug and Cosmetic Act in relation to chemistry manufacturing and controls procedures and may be approved from this standpoint. The product is to carry a 18 month expiration date.

TS/ 11/8/99
Dan Boring, R.Ph., Ph.D., Review Chemist for HFD-530

APPEARS THIS WAY
ON ORIGINAL

Concurrence: TS/ 11/8/99
HFD-530-/SMiller

- cc:
- NDA 21-087 Original
- HFD-530 Division File
- HFD-830/CChen
- HFD-530/PRajagopalan

- HFD-530/DBoring
- HFD-530/SMiller
- HFD-530/JMurray
- HFD-530/NBattula

- HFD-530/GCarmouze
- HFD-530/TWu
- HFD-530/IYuen

APPEARS THIS WAY
ON ORIGINAL