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

NDA#: 21-087

CHEMISTRY REVIEW #: 1  
DATE REVIEWED: 10/4/99

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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 influenzas A and B

DOSAGE FORM/STRENGTH: Capsule/75 mg

ROUTE OF ADMINISTRATION: Oral

CHEMICAL NAME/STRUCTURAL FORMULA:

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

Mol. Form. - C_{16}H_{28}N_{2}O_{4}
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.

Dan Boring, R.Ph., Ph.D., Review Chemist for HFD-530

Concurrence:
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/TYuen