

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21036

CHEMISTRY REVIEW(S)

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

NOV 22 1999

NDA#: 21-036

CHEMISTRY REVIEW #: 1 DATE REVIEWED: 6/16/99

SUBMISSION TYPE DOCUMENT DATE CDER DATE ASSIGNED DATE

Original	10/26/98	10/28/98	10/29/98
Amendment, BC	3/2/99	3/3/99	3/11/99
Amendment, BC	4/30/99	5/3/99	5/6/99
Amendment, BC	5/7/99	5/10/99	5/12/99
Amendment, BC	6/15/99	6/16/99	6/17/99
Amendment, BC	7/13/99		7/13/99

NAME & ADDRESS OF SPONSOR: Glaxo-Wellcome, Inc
 Five Moore Drive
 Research Triangle Park, NC 27709

DRUG PRODUCT NAMES:

Proprietary Relenza®
 Nonproprietary zanamivir for inhalation
 Code Name

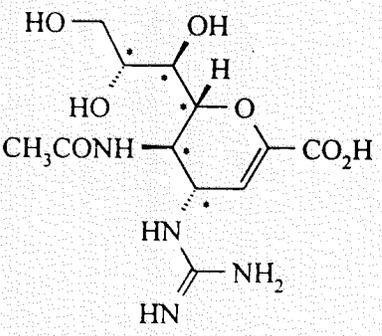
PHARMACOLOGICAL CATEGORY: Viral neuraminidase inhibitor

INDICATION: Treatment of influenza's A and B

DOSAGE FORM/STRENGTH: Dry powder inhaler/5 mg per blister
 4 blister per Rotadisk®

ROUTE OF ADMINISTRATION: Inhalation

CHEMICAL NAME/STRUCTURAL FORMULA:



5-(Acetylamino)-4-[(aminoimino-methyl)amino]-2,6-anhydro-3,4,5-trideoxy-D-glycero-D-galacto-non-2-enonic acid.
 M.W. - 332.3

Mol. Form. - C₁₂H₂₀N₄O₇

SUPPORTING DOCUMENTS:

IND
IND

DMF's
HFD-180 and have no outstanding issues.

RELATED DOCUMENTS:

Chemistry, Manufacturing and Controls consults provided by Dr. Dale Koble, reviewing chemist, Division of Pulmonary Drug Products, HFD-570.

CONCLUSIONS & RECOMMENDATIONS:

This application, as amended, is in conformance with section 505(b) in relation to chemistry manufacturing and controls procedures and may be approved from this standpoint. The product is to carry a 36 month expiration date.

IS/ 11/22/99
Dan Boring, R.Ph., Ph.D., Review Chemist for HFD-530

APPEARS THIS WAY
ON ORIGINAL

Concurrence: IS/ 11-22-99
HFD-530-/SMiller

- cc: NDA 21-036 Original HFD-530/DBoring HFD-530/SLynche
- HFD-530 Division File HFD-530/SMiller HFD-530/BStyrt
- HFD-830/CChen HFD-530/SKukich HFD-530/KMWu
- HFD-530/KReynolds HFD-530/LIacono-Connors

APPEARS THIS WAY
ON ORIGINAL