

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number** 21-036/S-001

**CHEMISTRY REVIEW(S)**

YOCKS

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

APR 18 2000

NDA#: 21-036

CHEMISTRY REVIEW #: 1

DATE REVIEWED: 4/12/00

**SUBMISSION TYPE** **DOCUMENT DATE** **CDER DATE** **ASSIGNED DATE**

Supplement S-001

10/25/99

4/10/00

**NAME & ADDRESS OF SPONSOR:**

Glaxo-Wellcome, Inc  
Five Moore Drive  
Research Triangle Park, NC 27709

**DRUG PRODUCT NAMES:**

Proprietary  
Nonproprietary  
Code Name

Relenza®  
zanamivir for inhalation

**PHARMACOLOGICAL CATEGORY:**

Viral neuraminidase inhibitor

**INDICATION:**

Treatment of influenza's A and B in children  
aged 5 - 12.

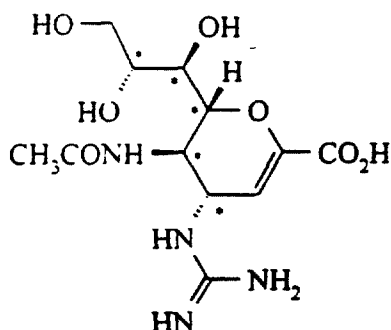
**DOSAGE FORM/STRENGTH:**

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. - C<sub>12</sub>H<sub>20</sub>N<sub>4</sub>O<sub>7</sub>

**SUPPORTING DOCUMENTS:**



GlaxoWellcome  
GlaxoWellcome

zanamivir for inhalation  
zanamivir for inhalation

Chemist review 1  
Chemist review 1

RELATED DOCUMENTS:

None

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.

/S/ 4/18/00  
 Dan Boring, R.Ph., Ph.D. Review Chemist for HFD-530

## Concurrence:

HFD-530-/SMiller

cc:

NDA 21-036 Original

HFD-530 Division File

HFD-830/CChen

HFD-530/KReynolds

/S/

HFD-530/DBoring

HFD-530/SMiller

HFD-530/SKukich

HFD-530/LIacono-Connors

HFD-530/SLynche Yoerg

HFD-530/BStyr

HFD-530/KMWu

**APPEARS THIS WAY  
 ON ORIGINAL**