

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-550/S-012

CHEMISTRY REVIEW

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

NDA #: 20-550/SE2-012

CHEMISTRY REVIEW #: 1

DATE REVIEWED 17-JAN-01

| <u>SUBMISSION TYPE</u> | <u>DOCUMENT DATE</u> | <u>CDER DATE</u> | <u>ASSIGNED DATE</u> |
|------------------------|----------------------|------------------|----------------------|
| SE2012(Original) | 30-AUG-00 | 31-AUG-00 | NA |

NAME/ADDRESS OF APPLICANT: GlaxoWellcome Inc..
Five Moore Drive
Research Triangle Park, NC 27709

DRUG PRODUCT NAME

| | |
|--------------------------------|----------------------------|
| <u>Proprietary:</u> | VALTREX™ |
| <u>Nonproprietary:</u> | Valacyclovir hydrochloride |
| <u>Code Name/#:</u> | 256U87 hydrochloride |
| <u>Chem. Type/Ther. Class:</u> | 2S |

PHARMACOLOGICAL CATEGORY: Antiviral

INDICATION: Treatment of initial episodes of genital herpes

DOSAGE FORM/STRENGTH: Caplets/500 mg & 1000 mg

ROUTE OF ADMINISTRATION: PO

CHEMICAL NAME/STRUCTURAL FORMULA:

L-valine, 2-[(2-amino-1,6-dihydro-6-oxo-9H-purin-9-yl)methoxy]ethyl ester, monohydrochloride

Molecular Weight: 360.80 324.34 (free base)

Empirical Formula: C₁₃H₂₀N₆O₄ HCl C₁₃H₂₀N₆O

SUMMARY/CONCLUSIONS/RECOMMENDATIONS:

This supplement provides for a labeling indication for a shorter treatment course of three days for VALTREX caplets in the treatment of recurrent episodes of genital herpes. The chemistry section of the proposed labeling remains the same and is found acceptable.

In conclusion, the chemistry section for SE2012 is approved from a CMC standpoint.

Ko-Yu Lo, Ph.D., Review Chemist

Concurrence:

HFD-530/SMiller

cc:

Orig. NDA 20-550

HFD-530/Pharm

HFD-530/Div. File

HFD-530/SMiller

HFD-530/KYLo

HFD-530/CSO

HFD-530/SMiller

HFD-530/MO

/s/

Ko-yu Lo

1/26/01 10:29:56 AM

CHEMIST

Added to DFS by SPM for K-YL

Stephen Paul Miller

2/5/01 10:40:27 AM

CHEMIST