020487_5004

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-487 /S-004

Trade Name: Valtrex®

Generic Name: (valacyclovir hydrochloride)

Sponsor: Glaxo Wellcome Inc.

Approval Date: January 13, 1997

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APPLICATION NUMBER:

20-487 /S-004

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Reviews / Information Included in this NDA Review.

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Final Printed Labeling	X
Medical Review(s)	X
Chemistry Review(s)	
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	X

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APPLICATION NUMBER:

20-487 /S-004

APPROVAL LETTER

NDA 20-487/S-004

JAN 13 1997

Glaxo Wellcome Inc.
Attention: Robert S. Watson
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Watson:

We acknowledge your December 16, 1996 supplemental New Drug Application received on December 17, 1996 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VALTREX® (valacyclovir hydrochloride) Caplets.

This supplemental application provides for changes under the CLINICAL PHARMACOLOGY: Clinical Trials: *Herpes Zoster Infections* section.

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Should you have any questions, please contact Mr. David Clinton Staten, Jr., Regulatory Health Manager, at (301) 827-2335

Sincerely yours,

1-10-97

Donna J. Freeman, M.D.
Acting Director
Division of Anti-Viral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Appears This Way
On Original