020487_5005

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-487 /S-005

Trade Name: Valtrex®

Generic Name: (valacyclovir hydrochloride)

Sponsor: GlaxoSmithKline

Approval Date: December 3, 2004

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APPLICATION NUMBER:

20-487 /S-005

CONTENTS

Reviews / Information Included in this NDA Review.

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

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APPLICATION NUMBER:

20-487 /S-005

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-487/S-005

GlaxoSmithKline
Attention: Sherman N. Alfors
Director, Antiviral/Antibacterial
US Regulatory Affairs
PO Box 13398
Five Moore Drive
Research Triangle Park
North Carolina 27709

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated February 19, 2004, received February 20, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valtrex® (valacyclovir hydrochloride) 500 mg and 1000 mg Caplets.

We acknowledge receipt of your submissions dated September 7, 2004 and November 11, 2004.

This supplemental new drug application provides for the revision of the PRECAUTIONS: Nursing Mothers subsection of the labeling for this drug product. The proposed wording is based on the results of a study which you have provided. Results from this study reported serum and human breast milk concentrations, ratios of serum to milk at different time points, as well as acyclovir concentrations from infant urine following maternal administration of Valtrex®.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 11, 2004.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call Nitin Patel, R.Ph., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research