

020487_5002

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-487 / S-002

Trade Name: Valtrex®

Generic Name: (valacyclovir hydrochloride)

Sponsor: Burroughs Wellcome Co.

Approval Date: September 8, 1995

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APPLICATION NUMBER:

20-487 /S-002

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APPROVAL LETTER

SEP 8 1995

NDA 20-487/S-002

Burroughs Wellcome Co.
3030 Cornwallis Road
P.O. Box 12700
Research Triangle Park, NC 27709
Attention: Mr. S. Wayne Talton
Assistant Director, Drug Regulatory Affairs CMC

Dear Mr. Talton:

Please refer to your supplemental New Drug Application dated August 29, 1995, submitted pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act for VALTRESX® (valacyclovir hydrochloride) Caplets, 500 mg and 1000 mg.

The supplemental application provides for a revision of the dissolution specification for VALTRESX Caplets, 500 mg, from the currently approved $Q = \text{---}$ in 30 minutes to $Q = \text{---}$ in 45 minutes.

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 set forth under 21 C.F.R. §314.80 and §314.81 for an approved NDA.

Sincerely yours,



Chi-wan Chen, Ph.D.
Supervisory Chemist
Division of Antiviral Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
HFD-530 NDA 20-487
HFD-530 Division File
HFD-530/CChen
HFD-530/KYLo
HFD-530/TCvetkovich
HFD-530/BDavit
HFD-530/DStaten

APPROVAL

Appears This Way
On Original