

020487 s_003

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Approval Package for:

APPLICATION NUMBER:

20-487 / S-003

Trade Name: Valtrex®

Generic Name: (valacyclovir hydrochloride)

Sponsor: GlaxoWellcome Co.

Approval Date: August 8, 1996

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Reviews / Information Included in this NDA Review.

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APPROVAL LETTER

AUG 9 1996

NDA 20-487/S003

Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709
Attention: Mr. Leo Lucisano
Assistant Director, Regulatory Affairs

Dear Mr. Lucisano:

Please refer to your supplemental New Drug Application dated April 9, 1996, submitted pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act for VALTREX® (valacyclovir hydrochloride) Caplets, 500 mg and 1000 mg. We acknowledge receipt of your amendment dated July 8, 1996.

The supplemental application provides for a change on the particle size specification and test method for colloidal silicon dioxide used as an excipient in VALTREX Caplets.

We have completed the review of this supplemental application as amended 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 CFR §314.80 and §314.81 for an approved NDA.

Sincerely yours,



Chi-wan Chen, Ph.D.
Chemistry Team leader, DNDC III
Division of Antiviral Drug Products (HFD-530)
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

cc:
NDA 20-487
HFD-530 Division File
HFD-530/CChen
HFD-530/KYLo
HFD-530/CSO
HFD-830/ESheinin

APPROVED

**Appears This Way
On Original**