

# **CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**20-487 /S-004**

**ADMINISTRATIVE DOCUMENTS**  
**AND**  
**CORRESPONDENCE**

GlaxoWellcome

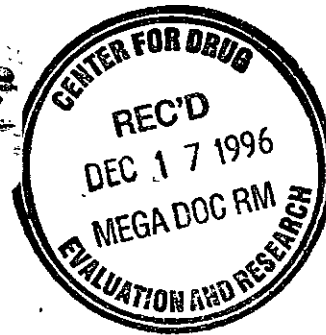
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NDA NO. 20487 REF. NO. S-004  
NDA SUPPL FOR Labeling

December 16, 1996

NDA NO. 20487  
NDA SUPPL FOR Labeling



Donna J. Freeman, M.D.  
Acting Director, Division of Antiviral Drug Products  
Attn: Document Control Room  
HFD-530  
Food and Drug Administration  
Fourth Floor  
9201 Corporate Blvd.  
Rockville, MD 20850

Re: NDA 20-487; VALTREX® (valacyclovir hydrochloride) Caplets for Herpes Zoster Virus  
Special Supplement: Changes Being Effected

Dear Dr. Freeman:

Reference is made to the November 18, 1996, letter of commitment regarding a change in labeling for Valtrex and to subsequent communications on this subject including fax transmissions dated November 18, 19, and 25, and December 5 and 9.

We are submitting herewith 12 copies of a final printed package insert which has been revised under CLINICAL PHARMACOLOGY: Clinical Trials: *Herpes Zoster Infections*. As agreed with Dr. Rachel Behman and Mr. David Staten, the last sentence of the paragraph has been replaced with the following sentence:

[ ]

A copy of the draft revised labeling is included behind Tab 1. All revisions from the current insert are indicated with revision bars in the right-hand margin. Added text is underlined; deleted text is lined through. Also included is a diskette in Word for Windows 6.0 which contains a revision-marked copy and a clean copy of the insert.

This submission is provided in duplicate with one desk copy being provided directly to Mr. David Staten. If there are any questions, please contact me at 919-483-6972.

Sincerely,

Robert S. Watson  
Product Director  
Regulatory Affairs

Glaxo Wellcome Inc.

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