






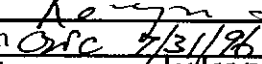
**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**20-487 /S-003**

**CHEMISTRY REVIEW(S)**

JUL 31 1996

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION HFD-530	2. NDA NUMBER 20-487
3. NAME AND ADDRESS OF APPLICANT (City and State) GlaxoWellcome Inc. Five Moore Drive Research Triangle Park, NC 27709		4. AF NUMBER	
		5. SUPPLEMENT(S)	
		NUMBER(S) S-003	DATE(S) 4/9/96
6. NAME OF DRUG VALTRES <sup>R</sup>		7. NONPROPRIETARY NAME Valacyclovir hydrochloride	
8. SUPPLEMENT(S) PROVIDES FOR: A change on particle size specification and test method for colloidal silicon dioxide in VALTRES Caplets		9. AMENDMENTS AND OTHER (Reports, etc) DATES 7/8/96	
10. PHARMACOLOGICAL CATEGORY Antiviral	11. HOW DISPENSED  X  Rx     OTC		12. RELATED IND/NDA/DMF(S)
13. DOSAGE FORM (S) Caplets		14. POTENCY(IES) 500 mg, & 1000 mg	
15. CHEMICAL NAME AND STRUCTURE L-valine, 2-[(2-amino-1,6-dihydro-6-oxo-9H-purin-9-yl)methoxy]ethyl monohydrochloride		16. RECORDS AND REPORTS Current     Yes     No Reviewed     Yes     No	
17. COMMENTS  GlaxoWellcome (GW) proposes to change the currently approved particle size specification and test method for colloidal silicon dioxide in VALTRES Caplets to one that is consistent with that used by _____ the manufacturer of this excipient material.      			
18. CONCLUSIONS AND RECOMMENDATIONS  _____ specification and _____ test method for colloidal silicon dioxide were found acceptable. From a control standpoint, S003 is approved. A draft approval letter is attached to this review.			
19. REVIEWER			
NAME Ko-Yu Lo, Ph.D.		SIGNATURE 	DATE COMPLETED 7/26/96
20. CONCURRENCE: HFD-530/CChen 			
DISTRIBUTION	<input checked="" type="checkbox"/>	Original Jacket	<input checked="" type="checkbox"/>
			KYLo
			<input checked="" type="checkbox"/>
			CChen
			<input checked="" type="checkbox"/>
			Division File
			<input checked="" type="checkbox"/>
			CSO

NDA 20-487/S003

## DRAFT APPROVAL LETTER

GlaxoWellcome 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<sup>R</sup> (valacyclovir hydrochloride) Capsules, 500 mg and 1000 mg. We acknowledged receipt of your amendment dated July 8, 1996.

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

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.  
Chemistry Team leader, DNDC III  
Division of Antiviral Drug Products  
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**

**WITHHOLD** 9 **PAGE(S)**

Chemistry Review