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)	DATE(S)
S-003	4/9/96

6. NAME OF DRUG
VALTREX[R]

7. NONPROPRIETARY NAME
Valacyclovir hydrochloride

8. SUPPLEMENT(S) PROVIDES FOR:
A change on particle size specification and test method for colloidal silicon dioxide in VALTREX 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 VALTREX 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	SIGNATURE	DATE COMPLETED
Ko-Yu Lo, Ph.D.	Kenyu Lo	7/26/96

20. CONCURRENCE: HFD-530/CChen Orc 7/31/96

DISTRIBUTION						
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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^{R} (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