

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-487 /S-002

ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE

ORIGINAL

NDA NO. 20487 REF. NO. 002
NDA SUPPL FOR SCS



Burroughs Wellcome Co.

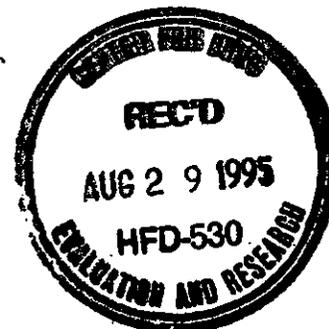
3030 Cornwallis Road
P. O. Box 12700
Research Triangle Park, N.C. 27709-2700

Telex: 5109270915
Tabloid RAL
Telephone: 919-248-3000

August 29, 1995

David W. Feigal, Jr., M.D., M.P.H., Director
Division of Antiviral Drug Products
Attn: Document Control Room
Food and Drug Administration
HFD-530, NLRC, 200
5516 Nicholson Lane
Kensington, MD 20895

*approved
9/8/95
Kouym*



**Re: NDA 20-487; VALTREX® (valacyclovir hydrochloride) Caplets for Herpes Zoster Virus
Supplemental Application: CMC
Expedited Review Requested**

Dear Dr. Feigal:

We submit herewith a Supplemental New Drug Application to provide for a revised dissolution specification for VALTREX Caplets, 500 mg.

Reference is made to telephone conversations held on August 23 and 25, 1995, between Dr. Ko-yu Lo, of your Division, and Mr. Wayne Talton, of our firm, concerning the dissolution specification. Reference is also made to a preliminary data package submitted to Dr. Lo by telefax on August 24, 1995.

As discussed with Dr. Lo, we submit this supplement for "Expedited Review" and wish to request a telephone conference on September 7 or 8, 1995, to discuss our proposed dissolution specification of Q: — in 45 minutes for VALTREX Caplets, 500 mg.

We certify that a Field Copy of this supplement has been provided to our FDA district office. If you should require any additional information, please do not hesitate to contact me at (919) 315-8548.

Sincerely,

S. Wayne Talton
Assistant Director
Regulatory Affairs CMC

cc: Dr. K. Lo, HFD-530

REVIEWS COMPLETED	
<hr/>	
CSO ACTION:	
<input checked="" type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I.
<hr/>	
CSO INITIALS	DATE



Food and Drug Administration
Rockville MD 20857

Date *September 6, 1995*

NDA No. 20-487

*BURROUGHS WELLCOME COMPANY
3030 Cornwallis Road
P.O.Box 12700
Research Triangle Park, N.C. 27709-2700

Attention: S. Wayne Talton
Assistant Director
Regulatory Affairs CMC

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: VALTrex(valacyclovir hydrochloride)Caplets for Herpes Zoster Virus

NDA Number: 20-487

Supplement Number: SCS-002

Date of Supplement: August 29, 1995

Date of Receipt: August 29, 1995

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Attention: Document Control Room 254
5516 Nicholson Lane, HFD-530
Rockville, MD 20857

Sincerely yours,

Supervisory Consumer Safety Officer
Division of Anti-Viral Drug Products
Center for Drug Evaluation and Research

<u>NDA DOCUMENT PACKAGE</u>	
- Chemistry Supplement Document Component Checklist -	
NDA Number: 20-489 Supplement(s): S-002	Attach DSS Assignment Sheet or Action Package Checklist <input checked="" type="checkbox"/>
Chemistry Supplement Types: <input type="checkbox"/> SCF – Change in Formulation <input type="checkbox"/> SCE – Expiration Date Change <input type="checkbox"/> SCP – Control / Packaging Change <input type="checkbox"/> SCM – Manufacturing <input checked="" type="checkbox"/> SCS – Control / Stability	

COMPONENT	CHECK-OFF/NOTES
APPROVAL LETTER	✓
APPROVAL LETTER ACKNOWLEDGMENT	✓
LABELING <input type="checkbox"/> FINAL PRINTED LABELING <input type="checkbox"/> DRAFT LABELING CITED IN APPROVAL LETTER	NA
CHEMISTRY REVIEW(S)	NA
CORRESPONDENCE	✓
OTHER REVIEWS/CONSULTS	NA
Additional Notes:	

020487_5002