CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-154 / S-004

Trade Name: Videx

Generic Name: (didanosine)

Sponsor: Bristol Meyer Squibb

Approval Date: February 4, 1993

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APPLICATION NUMBER:

20-154 / S-004

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter	
Final Printed Labeling	
Medical Review(s)	
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	

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APPLICATION NUMBER:

20-154 / S-004

APPROVAL LETTER

DRAFT LETTER

NDA 20-154/S004

Bristol-Myers Squibb
2400 West Lloyd Expressway
Evansville, IN 47721
Attention: MS Marygale Ritzert
Assistant Director
Regulatory Affairs

Dear MS Ritzert:

Please refer to your supplemental New Drug Application dated April 30, 1992 submitted pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act for VIDEX Chewable/Dispersible Buffered Tablets.

The supplemental application provides for final printed cartons for 25 mg, 50 mg, 100 mg and 150 mg strengths of VIDEX Chewable/Dispersible Buffered Tablets.

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.
Supervisory Chemist
Division of Antiviral Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
NDA 20-154 Original
NDA 20-154 Division File
HFD-530/LRosenstein
HFD-530/RBehrman
HFD-530/CChen
HFD-530/KYLo
HFD-530/CSO

APPROVAL

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APPLICATION NUMBER:

20-154 / S-004

CHEMISTRY REVIEW(S)

25.1

SUPPLEMENTAL NDA CHEMIST'S REVIEW	1. ORGANIZATION HFD-530	2. NDA NUMBER 20-154

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
Bristol-Myers Squibb U.S. Pharmaceutical
and Mead Johnson Nutritional Group
2400 West Lloyd Expressway
Evansville, IN 47721

FEB 5 1993

4. AF NUMBER

5. SUPPLEMENT(S)

NUMBER(S)	DATE(S)
SCP-004	4/30/92

6. NAME OF DRUG
VIDEX

7. NONPROPRIETARY NAME
Didanosine

8. SUPPLEMENT(S) PROVIDES FOR:
Final printed cartons for VIDEX Chewable/Dispersible Buffered Tablets

9. AMENDMENTS AND OTHER *(Reports, etc)* **DATES**

10. PHARMACOLOGICAL CATEGORY
Antiviral

11. HOW DISPENSED
|X| Rx | | OTC

12. RELATED IND/NDA/DMF(S)

13. DOSAGE FORM(S)
Chewable/Dispersible Buffered Tablets

14. POTENCY(IES)
25 mg, 50 mg, 100 mg, and 150 mg

15. CHEMICAL NAME AND STRUCTURE
2',3'-dideoxyinosine

16. RECORDS AND REPORTS
Currrent
| | Yes | | No
Reviewed
| | Yes | | No

17. COMMENTS

SCP-004 provides for final printed cartons for 25 mg, 50 mg, 100 mg, and 150 mg strengths of VIDEX Chewable/Dispersible Buffered Tablets. The carton labels are the same as those approved for the immediate containers. When the NDA was approved, the drug products were not packaged in a carton.

This supplement falls into the category **"Special Supplement-Changes Being Effected"** under 21 C.F.R. § 314.70 (c).

18. CONCLUSIONS AND RECOMMENDATIONS

Carton labels are found to be ADEQUATE. From CMC standpoint, SCP 004 is APPROVABLE.
A draft approval letter is attached to this review.

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Ko-Yu Lo, Ph.D.	Ko-Yu Lo	2/2/93

20. CONCURRENCE: HFD-530/LRosenstein 2/6/93 HFD-530/CChen CMC 2/3/93

DISTRIBUTION						
	X	Original Jacket	X	Division File	X	Reviewer
	X	LRosenstein	X	CChen	X	CSO