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# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package

### *APPLICATION NUMBER:*

**20-154/S-032, S-033**

**20-155/S-023, S-024**

**20-156/S-024, S-025**

*Trade Name:* Videx®

*Generic Name:* (didanosine)

*Sponsor:* Bristol-Myers Squibb Company

*Approval Date:* July 24, 2000

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## *APPLICATION NUMBER:*

**20-154/S-032, S-033**

**20-155/S-023, S-024**

**20-156/S-024, S-025**

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<b>Approvable Letter</b>	
<b>Final Printed Labeling</b>	<b>X</b>
<b>Medical Review(s)</b>	<b>X</b>
<b>Chemistry Review(s)</b>	
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## ***APPLICATION NUMBER:***

**20-154/S-032, S-033**

**20-155/S-023, S-024**

**20-156/S-024, S-025**

## **APPROVAL LETTER**

NDA 20-154/S-032, S-033  
NDA 20-155/S-023, S-024  
NDA 20-156/S-024, S-025

JUL 24 2000

Bristol-Myers Squibb Company  
Attention: Cynthia F. Piccirillo  
Associate Director, Worldwide Regulatory Affairs  
5 Research Parkway  
Wallingford, CT 06492

Dear Ms. Piccirillo:

Please refer to your supplemental new drug applications dated January 14, 2000, and March 21, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX® (didanosine) Chewable/Dispersible Tablets, Buffered Powder for Oral Solution, and Pediatric Powder for Oral Solution.

We acknowledge receipt of your submissions dated:

January 14, 2000	March 21, 2000	March 24, 2000
March 30, 2000	April 19, 2000	April 20, 2000
April 21, 2000	April 25, 2000	April 28, 2000
May 18, 2000	May 22, 2000	May 24, 2000
May 30, 2000	May 31, 2000	June 9, 2000
July 12, 2000	July 14, 2000	July 18, 2000

S-032, S-023, S-024, dated January 14, 2000

These Changes Being Effected" supplemental new drug applications provide for clarification of the utilization of the VIDEX® 200 mg strength chewable/dispersable tablet as part of a once daily regimen, and are incorporated in the DOSAGE AND ADMINISTRATION section of the VIDEX® label.

S-033, S-024, S-025, dated March 21, 2000

These supplemental new drug applications provide for the inclusion of a detailed description of the 48-week final results of study A1454-148 in the VIDEX® label and VIDEX® patient package insert, and the recommendation that twice-daily administration of VIDEX® is the preferred dosing frequency for VIDEX®.

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that VIDEX® is safe and effective for use as recommended in the agreed upon labeling text submitted July 21, 2000. The agreed upon labeling text submitted July 21, 2000, supercedes labeling text

submitted on January 14, 2000. Accordingly, these supplemental new drug applications are approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the agreed upon labeling text (package insert submitted July 21, 2000, and patient package insert submitted July 21, 2000).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Individually mount ten copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplemental NDA number." Approval of this submission by FDA is not required before labeling is used.

In addition, a "Dear Health Care Practitioner" letter outlining the results of study A1454-148 has been requested, and you have committed to distribution of the agreed upon letter within fourteen days of the date of approval of these supplemental applications.

We request that you submit a copy of the requested "Dear Health Care Practitioner" letter, issued to physicians and others responsible for patient care, to this NDA and a copy to the following address:

MED WATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Destry M. Sullivan, MS, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

Heidi M. Jolson, M.D., M.P.H.  
Director  
Division of Antiviral Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research