



NDA 20-154/S-037  
NDA 20-155/S-028  
NDA 20-156/S-029  
NDA 21-183/S-003

Bristol-Myers Squibb Company  
Attention: Marie-Laure Papi  
Associate Director, Worldwide Regulatory Affairs  
5 Research Parkway  
Wallingford, CT 06492

Dear Ms. Papi:

Please refer to your supplemental new drug applications dated June 1, 2001, received June 1, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX® (didanosine) Buffered Tablets, VIDEX® (didanosine) Buffered Powder for Oral Solution, VIDEX® (didanosine) Pediatric Powder, and for VIDEX® EC (didanosine) Delayed Release Capsules.

We acknowledge receipt of your submissions dated August 1, 2002, September 13, 2001, November 30, 2001, and March 28, 2002.

These supplemental new drug applications provide for the use of VIDEX® (didanosine) Buffered Tablets, VIDEX® (didanosine) Buffered Powder for Oral Solution, and VIDEX® (didanosine) Pediatric Powder in pediatric patients from two weeks to eight months of age.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted March 28, 2002, patient package insert submitted March 28, 2002).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements for NDA 20-154/S-037, 20-155/S-028, 20-156/S-029." Approval of these submissions by FDA is not required before the labeling is used.

Additionally, we acknowledge your intent to collect long-term follow up safety information for participants enrolled in your study number AI455-094, as was specified in your Written Request for VIDEX® (didanosine), dated August 5, 1999.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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, call Destry M. Sullivan, M.S., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

*{See appended electronic signature page}*

Jeffrey Murray, M.D.  
Acting Director  
Division of Antiviral Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
Jeffrey Murray  
4/1/02 04:27:10 PM