DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

20-154/S-044
20-155/S-034
20-156/S-035
21-183/S-010

Bristol-Myers Squibb
Pharmaceutical Research Institute
Attention: Lamine Messaoudi, DVM
Manager, Global Regulatory Affairs
5 Research Parkway, P.O. Box 5100
Wallingford,CT 06492-7660

Dear Dr, Messaoudi:

Please refer to your supplemental new drug applications dated July 18, 2003, received July 21, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX® (didanosine) Chewable/dispersible Tablets, VIDEX® (didanosine) Buffered Powder for Oral Solution, VIDEX® (didanosine) Pediatric Powder for Oral Solution, and VIDEX® (didanosine) Delayed-Release Capsules Enteric Coated.

We acknowledge receipt of your submissions dated December 19, 2003, and January 21, 2004.

These supplemental new drug applications provide for the inclusion of pharmacokinetic, precautionary, and dosage and administration information related to coadmininistration of didanosine and tenofovir disoproxil fumarate.

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 January 21, 2004, patient package insert submitted January 21, 2004).

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 supplemental NDAs 20-154/S-044, 20-155/S-034, 20-156/S-035, 21-183/S-010." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
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 Sillivan, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Jeffrey Murray, M.D.
Deputy 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
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