DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-154/S-042
NDA 20-155/S-032
NDA 20-156/S-033
NDA 21-183/S-007

Bristol-Myers Squibb
Attention: Marie-Laure Papi
Senior Regulatory Associate
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

Dear Ms. Papi:

Please refer to your supplemental new drug applications dated January 15, 2003, received January 16, 2003, 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 VIDEX® (didanosine) Delayed-Release Capsules Enteric Coated.

We acknowledge receipt of your submissions dated January 28, 2003, and January 31, 2003.

These supplemental new drug applications provide for the inclusion of precautionary information about the potential risk of co-administration of didanosine and ribavirin to patients who are co-infected with HIV and HCV to the VIDEX® and VIDEX® EC package inserts and patient package inserts.

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 28, 2003, patient package insert submitted January 28, 2003).

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-042, 20-155/S-032, 20-156/S-033, 21-183/S-007." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final

print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

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

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
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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