DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

21-183/S-005, S-006

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 application dated May 31, 2002, received June 3, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX® EC (didanosine) Delayed Release Capsules.

We acknowledge receipt of your submissions dated August 30, 2002, and September 19, 2002.

The supplemental new drug application provides for changes to the VIDEX® EC package insert and patient package insert that describe the potential risk of didanosine-related adverse events when VIDEX® EC and ribavirin are co-administered.

Please also refer to your supplemental new drug applications dated July 11, 2002, received July 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX® EC (didanosine) Delayed Release Capsules.

We acknowledge receipt of your submissions dated July 25, 2002, and September 19, 2002.

The supplemental new drug application provides for changes to the VIDEX® EC package insert and patient package insert that describe the results of pharmacokinetic drug interaction studies in which significant increases in didanosine exposures were observed, and the potential risk of didanosine-related adverse events when VIDEX® EC and tenofovir disoproxil fumarate are co-administered.

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 September 19, 2002, patient package insert submitted September 19, 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 supplement NDA 21-183/S-005, S-006." 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/

Debra Birnkrant
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NDA 21-183