NDA 20-154/S-049
NDA 20-155/S-038
NDA 20-156/S-039
NDA 21-183/S-015

CHANGES BEING EFFECTED

Bristol-Myers Squibb Pharmaceutical Company
Attention: Nancy Mason-Liddil
Associate Director, Global Regulatory Sciences
5 Research Parkway
Signature 91 Building, 3SIG-513
Wallingford, CT 06492

Dear Ms. Mason-Liddil:

Please refer to your supplemental new drug applications dated January 27, 2006 received January 30, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following products:

- Videx® (didanosine) Chewable/Dispersible Buffered Tablets 25 mg, 50 mg, 100 mg, 150mg, and 200 mg
- Videx® (didanosine) Buffered Powder for Oral Solution 45 mg, 67mg, 100 mg, 167 mg, 250 mg, and 375 mg
- Videx® (didanosine) Pediatric Powder for Oral Solution 2mg/bottle, and 4gm/bottle
- Videx® EC (didanosine) Delayed Release Capsules 125 mg, 200 mg, 250 mg, and 400 mg

We acknowledge receipt of your amendments dated July 31, 2006.

These "Changes Being Effected" supplemental new drug applications provide the addition of the statement regarding immune reconstitution syndrome in the PRECAUTIONS section of the package insert for Videx® and Videx EC® in response to a request from the FDA. In addition, the following labeling changes are made:

- Adding a warning statement regarding patients with preexisting liver disease
- Adding a warning/precaution statement regarding adverse events when coadministered with hydroxyurea
- Deleting Extra Strength Maalox® from the Method of Preparation **(**only for Videx®)
- Revising the cautionary statement for tenofovir/didanosine coadministration to add monitoring for clinical response

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 31, 2006.

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, call Monica Zeballos, Pharm.D., Regulatory Project Manager, at (301) 796-0840.

Sincerely yours,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Approved labeling (package insert and patient package insert) for Videx® and Videx EC®

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
8/18/2006 01:19:27 PM
NDA 21-183, 20-156, 20-155, 20-154