DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-412/S-027
NDA 20-413/S-018

Bristol-Myers Squibb Company
Attention: Nancy Mason-Liddil
Associate Director, Global Regulatory Strategy
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

Dear Ms. Mason-Liddil:

Please refer to your supplemental new drug application dated November 13, 2006, received November 14, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zerit® (stavudine) capsules and Zerit® (stavudine) Powder for Oral Solution.

We acknowledge receipt of your supplemental applications, submitted as "Supplement- Changes Being Effected", dated November 13, 2006.

These "Supplement-Changes Being Effected" supplemental applications include the following revisions to the package insert:

- Update warning statement to accurately reflect recommendations regarding the coadministration of stavudine, didanosine and hydroxyurea under the subheading of *Use with Didanosine and Hydroxyurea-Based Regimens* and in the Patient Information section.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted November 13, 2007, patient package insert submitted November 13, 2007).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-412/S-027, NDA 20-413/S-018**." Approval of this submission 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Monica Zeballos, Pharm.D., Regulatory Project Manager, at (301) 796-2013.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Division Director
Division of Antiviral Products
Office of Antimicrobial Products
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
4/20/2007 07:55:49 AM