



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 Mrs. 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 also refer to the approval letter dated April 20, 2007 for the supplemental new drug application dated November 13, 2006 submitted as "Supplement- Changes Being Effected".

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.

This letter is being sent to advise you of the correction made to this approval letter. In the original approval letter dated April 20, 2007, you were asked to submit the FPL. However, since the submission included all labeling components and was approved without corrections, FPL does not have to be submitted. Request for electronic version of FPL has been removed from the approval letter.

You will receive a replacement action letter with the aforementioned correction. The date of the action will be unchanged, but the signature time will be one minute later to permit differentiation between the letters.

If you have any questions, call Jaewon Hong, Regulatory Project Manager, at 301-796-2013.

Sincerely,

{See appended electronic signature page}

Anthony W. DeCicco, R.Ph.
Chief, Project Management Staff
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
6/6/2007 10:57:23 AM