DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-412/S-029
NDA 20-413/S-020

Lori A. Palmer
Associate Director, Global Regulatory Strategy
Bristol-Myers Squibb Company
P.O. Box 5100 Wallingford, CT
06492-7660

Dear Ms. Palmer:

Please refer to your supplemental new drug applications dated October 15, 2007, received October 15, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zerit™ (stavudine) capsules 15 mg, 20 mg, 30 mg and 40 mg and Zerit™ (stavudine) Powder for Oral Solution 1mg/mL.

These "Changes Being Effected" supplemental new drug applications add diabetes mellitus and hyperglycemia to the Adverse Reactions section and high blood sugar (hyperglycemia or diabetes) to the Patient Information section of the package insert.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 15, 2007.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Anne Marie Russell, Ph.D., Regulatory Project Manager, at (301) 796-2014.

Sincerely,

{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

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
4/14/2008 03:52:20 PM
NDA 20-412, 20-413