DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-412/S-030
NDA 20-413/S-021

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 16, 2007, received October 16, 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 delete two inactive ingredients, silicon dioxide and sodium lauryl sulfate, from Description 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 16, 2007.

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}

Hasmukh Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Hasmukh Patel

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