DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-412/S-032
NDA 20-413/S-023

Bristol-Myers Squibb Company
Attention: David L. Silberstein
Associate Director, Global Regulatory Science
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Silberstein:

Please refer to your supplemental new drug applications (NDAs) dated July 11, 2008, received July 11, 2008, 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.

We also acknowledge receipt of your submissions dated October 1, 2008.

These "Changes Being Effected" supplemental new drug applications provide for the following changes in the Patient Package Insert under, "What else should I know about ZERIT?" subsection:

- Addition of language regarding keeping the drug away from pets.
- Revisions to the disposal instructions that now states: "Do not keep medicine that is out of date or that you no longer need. Dispose of unused ZERIT through community take-back disposal programs when available or by placing it in an unrecognizable closed container in the household trash."

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 content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on October 1, 2008.

The final printed labeling (FPL) must be identical to the submitted labeling (patient package insert submitted October 1, 2008).

In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Amalia Himaya, Regulatory Project Manager, at (301) 796-3391.

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: labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Kendall Marcus

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