DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-412/S-023
NDA 20-413/S-014

Bristol-Myers Squibb Company
Attention: Lamine Messaoudi, D.V.M
Manager, Global Regulatory Science
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

Dear Mr. Messaoudi:

Please refer to your supplemental new drug applications dated December 23, 2003, received December 24, 2003 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 the amended submissions dated January 27, 2004 (2), April 1, 2004 (2), May 17, 2004 (2).

These supplement new drug applications provide labeling revisions to Microbiology and Precautions sections. Also, the following sections were updated for consistency with the Zerit XR labeling, as approved on December 31, 2002: Clinical Pharmacology section, Drug Interactions subsection, and Storage Conditions section.

We have completed the review of the supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the agreed-upon labeling (text for the package insert, text for the patient package insert, and immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and unapproved.

Please submit the copies of final printed labeling (FPL) electronically 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "**FPL for approved NDA 20-412/S-023 and NDA 20-413/S-014**." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Antiviral Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
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, please call Donald W. Reese, PharmD, MBA, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra B. Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV

Enclosure: Revised ZERIT Labeling (PI and PPI) dated 05/17/2004

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
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NDA 20-412, 20-413