DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-797/S-006
NDA 21-798/S-007

Bristol-Myers Squibb Company
Attention: Katherine Takaki, Ph.D.
Director, Global Regulatory Sciences
5 Research Parkway
Wallingford, CT 06492-7660

Dear Dr. Takaki:

Please refer to your supplemental new drug applications dated and received February 25, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BARACLUDE (entecavir) tablets and oral solution.

These "Changes Being Effected" supplemental new drug applications propose the following changes:

- Revise USPI to add a postmarketing experience section with the term "rash" as a reported adverse reaction
- Add "rash" to Patient Package Insert
- Revise wording in Patient Package Insert regarding the recommendation for disposal of unused medication to make it consistent with the guidelines from the White House Office of National Drug Policy)

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Within 14 days of the date of this letter, amend any pending applications for Baraclude (NDA 21-797/S-[redacted] and NDA 21-798/S[redacted]) with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert and patient package insert submitted February 25, 2008.

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 Elizabeth Thompson, Regulatory Project Manager, at (301) 796-0824.

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 (clean copy of approved label)

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
6/3/2008 10:45:56 AM
NDA 21-798, 21-797