DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-797/S-009
NDA 21-798/S-010

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 January 29, 2009, 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 the term "alopecia" as a reported adverse reaction in the ADVERSE REACTIONS, Postmarketing Experience section

- Revise wording in OVERDOSAGE section to indicate "limited" instead of "no" experience of entecavir overdosage reported in patients.

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.

CONTENT OF LABELING

Within 14 days of the date of this letter, amend (b) (4) with content of labeling in structured product labeling (SPL) format to include the changes approved in this application. (b) (4)

The final printed labeling (FPL) must be identical to the submitted labeling (package insert and patient package insert) submitted January 29, 2009.

LETTERS TO HEALTH CARE PROFESSIONALS
If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS
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/

Kendall Marcus
2/25/2009 09:54:39 PM
for Debra Birnkrant