DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 21-797/S-008
NDA 21-798/S-008

APPROVAL LETTER

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 September 26, 2008, received September 26, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Baraclude (entecavir) Tablets and Oral Solution.

We acknowledge receipt of your submissions dated January 7, 2009, February 13, 2009, March 11, 2009, June 2, 2009, June 10, 2009, June 11, 2009, June 15, 2009, and July 13, 2009.

These supplemental applications propose changes to the CLINICAL PHARMACOLOGY, Microbiology section of the package insert to include results from the long-term rollover study AI463901:

- Year 5 data on the genotypic and phenotypic analyses of isolates from entecavir-treated subjects from the resistance cohort

In addition, the following sections of the patient package insert were updated:

- What is the most important information I should know about BARACLUDE?
- What is BARACLUDE?
- What are the possible side effects of BARACLUDE?

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 enclosed agreed-upon labeling text.

CONTENT OF LABELING
The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert).

PROMOTIONAL MATERIALS
You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration

Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

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, MS, 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/

Jeffrey Murray

7/16/2009 04:03:43 PM