DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-972/S-036
NDA 21-360/S-024

SUPPLEMENT APPROVAL

Bristol Myers Squibb
Attention: Katherine Takaki, PhD
Director, Global Regulatory Strategy
5 Research Parkway, Room 251E, Mailstop 2CW-507
Wallingford, CT 06492

Dear Dr. Takaki:

Please refer to your Supplemental New Drug Application (sNDA) dated July 29, 2010, and received July 30, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sustiva ® (efavirenz) 50 mg and 200 mg capsules and 600 mg tablets.

These Prior Approval supplemental new drug applications propose to update the label to recommend against Sustiva use in patients with moderate to severe hepatic impairment and to add vertigo as an observed postmarketing event.

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

POSTMARKETING COMMITMENTS

The approval of these supplements fulfills the following postmarketing commitment (PMC) acknowledged in the September 17, 1998, approval letter:

752-8. Conduct and submit results of a multiple dose pharmacokinetics study in patients with hepatic impairment.

We remind you of the following postmarketing commitment acknowledged in the September 17, 1998, approval letter that is still open:

752-3. Firm agrees to continue with the development of their pediatric program, with emphasis on developing a liquid formulation along with obtaining safety, tolerability, pharmacokinetic and antiviral activity.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert and patient package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements and any annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.
The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) 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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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, please contact Venessa M Perry, MPH, Regulatory Project Manager, at 301.796.4891 or Venessa. Perry@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

/Kendall Marcus/
for Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

VENESSA M PERRY
11/30/2010

KENDALL A MARCUS
11/30/2010