



NDA 20972/S-040  
NDA 21360/S-028

## SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company  
Attention: Hwei-Gene Wang, Ph.D.  
Associate Director, Global Regulatory Sciences, US  
5 Research Parkway, Room 215U, Mailstop 2AW-708  
Wallingford, CT 06492

Dear Dr. Wang:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received July 15, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sustiva (efavirenz) Capsules, 50 and 200 mg and Sustiva (efavirenz) Tablets, 600 mg.

We acknowledge receipt of your amendments dated October 7, 2011, October 17, 2011, October 26, 2011, and December 8, 2011.

These Prior Approval supplemental new drug applications provide for the following updates to the Dosage and Administration and Drug Interactions Sections of the package insert:

If SUSTIVA is coadministered with rifampin to patients weighing 50 kg or more, an increase in the dose of SUSTIVA to 800 mg once daily is recommended.

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

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to, except with the revisions listed, the enclosed labeling (the package insert and the patient package insert,) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as 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 via 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 with the revisions listed approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **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 Sherly Abraham, R.Ph., Regulatory Project Manager, at (301) 796-3198.

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

Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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KENDALL A MARCUS  
12/19/2011