DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021986/S-009/S-010

SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company
Attention: Meenal Pai, Pharm.D.
5 Research Parkway
P.O. Box 5100, Mailstop 3SIG-3021
Wallingford, CT 06492

Dear Dr. Pai:

Please refer to your Supplemental New Drug Applications (sNDA) S-009 dated and received April 27, 2011, and S-010 dated and received May 18, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sprycel® (dasatinib) Tablets 20 mg, 50 mg, 70 mg, and 100 mg.

We acknowledge receipt of your amendments dated June 6, July 25, September 15, October 5 and 6, 2011.

These Prior Approval supplemental new drug applications provide for the following, S-009 provides for the revision of the product insert Section 6.4 Postmarketing Experience to include pulmonary arterial hypertension; S-010 provides for the revision of the product insert Section 13 Nonclinical Toxicology – Carcinogenesis, Mutagenesis, Impairment of Fertility to include the conclusions of a rat carcinogenicity study (DS07137).

We have completed our review of these supplemental applications, as amended. They are 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 the enclosed labeling text for the package insert and 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 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, 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 Amy Tilley, Regulatory Project Manager, at 301-796-3994.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Oncology Products 1
Office of Hematology Oncology Products
Center for Drug Evaluation and Research

ENCLOSURES:
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/

ROBERT L JUSTICE
10/07/2011