



NDA 021986/S-014

**SUPPLEMENT APPROVAL**

Bristol-Myers Squibb  
Attention: Kruti Patel, R.Ph.  
Associate Director, Global Regulatory Sciences  
P.O. Box 4000  
Princeton, NJ 08543

Dear Kruti Patel:

Please refer to your Supplemental New Drug Application (sNDA) dated September 17, 2013, received September 17, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sprycel (dasatinib) 20, 50, 70, 80, 100 and 140 mg tablets.

We acknowledge receipt of your amendments dated January 14 and 31; February 11 and 20, and April 18, 2014.

This "Prior Approval" supplemental new drug application proposes the following labeling changes:

Under WARNINGS AND PRECAUTIONS - Embryofetal toxicity,

USE IN SPECIFIC POPULATIONS - Pregnancy,

PATIENT COUNSELING INFORMATION - Pregnancy

- Based on post-marketing case reports of embryo fetal toxicity, BMS propose to update the current dasatinib WARNING AND PRECAUTIONS for use in pregnancy. The labeling is revised to be consistent with 21 CFR 201.57 (c) (9), (i), (A), (4).

Under NONCLINICAL TOXICOLOGY - Carcinogenesis, Mutagenesis, Impairment of Fertility:

- Proposal to include findings from exploratory peri- and post-natal development study in rats for completeness.

Under CLINICAL TRIALS - Imatinib Resistant or Intolerant CML or Ph+ ALL:

- Correction to text as per FDA request dated June 10 and June 11, 2013. This text was agreed by BMS in our response dated June 11, 2013 but it appears this was inadvertently not incorporated in the final labeling approved June 17, 2013.

**APPROVAL & LABELING**

We have completed our review of this supplemental application, 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 the enclosed labeling (text for the package insert, text for 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes 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 Lara Akinsanya, Regulatory Project Manager, at (301) 301-796-9634.

Sincerely,

*{See appended electronic signature page}*

Ann T. Farrell, M.D.  
Division Director  
Office of Hematology and Oncology 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/  
-----

ANN T FARRELL  
04/10/2014