



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

NDA 022072/S-002  
NDA 021986/S-005

**SUPPLEMENT APPROVAL**

Bristol Myers Squibb  
Attention: Meenal Pai, Pharm.D.  
Associate Director, Global Regulatory Service  
P.O. Box 5100  
Wallingford, CT 06492-7660

Dear Dr. Pai:

Please refer to your Supplemental New Drug Application (sNDA), dated October 22, 2008, received October 22, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sprycel®, (dasatinib) Tablets.

These “Changes Being Effected” supplemental new drug applications provide for revision of the Adverse Reactions section of the package insert to include discontinuation rate due to myelosuppression to 5%.

We have completed our review of these supplemental application. 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, 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 include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. “In patients who experienced severe myelosuppression, recovery generally occurred following dose interruption or reduction; permanent discontinuation of treatment occurred in ~~4~~5% of patients [*see Warnings and Precautions (5.1)*]”: “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 pending “Changes Being Effected” (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.

### **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 CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch  
Food and Drug Administration  
Suite 12B-05  
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 Allison Adams-McLean, Regulatory Project Manager, at (301) 796-3996.

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE(S):

Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21986	SUPPL-5	BRISTOL MYERS SQUIBB CO	SPRYCEL
NDA-22072	SUPPL-2	BRISTOL MYERS SQUIBB CO	SPRYCEL

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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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ROBERT L JUSTICE  
07/28/2010