DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021986/S-008 **ACCELERATED APPROVAL**

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

Dear Dr. Pai:

Please refer to your supplemental new drug application dated April 28, 2010, received and April 28, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sprycel® (dasatinib) Tablets.

We acknowledge receipt of your submissions dated June 7, June 25, June 30, July 28, August 13, August 25, October 14, October 25, and October 27, 2010.

This new drug application provides for the use of Sprycel® (dasatinib) for treatment of newly diagnosed adults with chronic myeloid leukemia (CML) in chronic phase.

We have completed the review of this supplemental application, as amended. According to the regulations for accelerated approval, we have concluded that adequate information has been presented to approve Sprycel® (dasatinib) for use as recommended in the agreed upon labeling text. Accordingly, the application is approved under 21 CFR 314 Subpart H. Approval is effective on the date of this letter. Marketing of this drug product and related activities are to be in accordance with the substance and procedures of the referenced accelerated approval regulations.

POSTMARKETING REQUIREMENTS UNDER 21 CFR 314.510 (SUBPART H)

Products approved under the accelerated approval regulations, 21 CFR 314.510, require further adequate and well-controlled trials to verify and describe clinical benefit. We remind you of your post marketing trial (Subpart H Phase 4 Requirements) specified in your submission dated October 21, 2010. This requirement along with any completion dates agreed upon, is listed below.

1699-1 To submit the final report (at least 60 months of follow-up) and data from CA180056 entitled “An Open-Label, Randomized, Multicenter Phase III Trial of Dasatinib versus Standard Dose Imatinib in the Treatment of Subjects with Newly Diagnosed Chronic Phase Philadelphia Chromosome Positive Chronic Myelogenous Leukemia.”

The timetable you submitted on October 21, 2010, states that you will conduct this trial according to the following schedule:

Protocol Submission:	by September 2009
Trial Completion:	by February 2014
Final Report and Dataset Submission:	by November 2014

Final reports should be submitted to this NDA as a supplemental application. For administrative purposes, all submissions relating to this postmarketing requirement must be clearly designated "**Postmarketing Requirements under Subpart H**."

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an Orphan designation, you are exempt from this requirement.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via 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, text for the patient package insert,). 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on September 23, 2010, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this

submission "**Final Printed Carton and Container Labels for approved NDA 021986**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

Immediately submit all promotional materials (both promotional labeling and advertisements) to be used within the first 120 days after approval. Send one copy to this division and two copies of the promotional materials and the package inserts directly 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

In addition, as required by 21 CFR 314.550, submit all subsequent promotional materials at least 30 days before the intended time of initial distribution of labeling or initial publication of the advertisement. Send two copies of the promotional materials and the package insert to the address above.

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 set forth under 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}

Ann T. Farrell, M.D.
Acting Director
Division of Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container 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
10/28/2010