



NDA 21-986/S-003, 22-072/S-001

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

Dear Ms. Pai:

Please refer to your supplemental new drug applications dated January 30, 2008, received January 30, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SPRYCEL® (dasatinib) Tablets.

These “Prior Approval” supplemental new drug applications provide for labeling and CMC information for a new tablet strength, 100 mg SPRYCEL® film-coated tablets.

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on January 30, 2008.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels 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 (October 2005)*. 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 21-986/S-003 and NDA 22-072/S-001.**” 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.

If you have any questions, call Rebecca McKnight, Regulatory Health Project Manager, at (301) 796-1765.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Eric Duffy
5/30/2008 05:01:55 PM