DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17588/S-036

SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company
Attention: Angela Glauberzon
Associate Director, Mature Products
P.O. Box 4000
Princeton, NJ 08543

Dear Ms. Glauberzon:

Please refer to your Supplemental New Drug Application (sNDA) dated August 24, 2009, received on August 24, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for CeeNu® (lomustine) Capsules.

We acknowledge receipt of your amendments dated July 7, 2011, May 25, 2012, September 7, 2012, October 24, 2012, November 12, 2012, November 19, 2012, November 20, 2012 and November 21, 2012.

The May 25, 2012, submission constituted a complete response to our November 17, 2011, action letter.

This "Changes Being Effected" (CBE) supplemental new drug application proposes to revise the Information for Patients, Dosage and Administration, and Directions to the Pharmacist sections of the package insert. In addition, this CBE proposes to revise the package design and carton and container labeling. The revisions were proposed in response to FDA concerns regarding administration errors reported for patients who have been prescribed CeeNu. This was determined to be the result of package, carton and container design and labeling issues.

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 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).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed.

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 none of these criteria apply to your application, you are exempt from this requirement.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

1967-1 To redesign the carton and container configuration to limit the net quantity per bottle to 5 (five) capsules in order to reduce or eliminate the possibility of administration errors. You will submit a CBE-30 Supplement that contains carton and container labeling revisions commensurate with the agreed upon labeling changes approved under supplement 36.

The timetable you submitted on November 12, 2012, states that you will complete this commitment according to the following schedule:

CBE-30 Supplement submission: June 2013

Submit chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii) you should include a status summary of your commitment in your annual report to this NDA. The status summary should include expected CBE-30 supplement submission date and any changes in plans since the last annual report. All submissions, including supplements, relating to this postmarketing commitment should be prominently labeled "**Postmarketing Commitment Submission-CBE-30 Supplement** or "**Postmarketing Commitment Correspondence**."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Mona Patel, Pharm.D., Regulatory Project Manager, at (301) 796-4236.

Sincerely,

{See appended electronic signature page}

Jeffery Summers, M.D.
Deputy Director for Safety
Division of Oncology Products 2
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

JEFFERY L SUMMERS
11/21/2012