DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-422/S-037

Bristol-Myers Squibb Company
Attention: Michael J. Theil
Group Manager, Global Regulatory Affairs, CMC
P.O. Box 191
New Brunswick, NJ 08903-0191

Dear Mr. Theil:

Please refer to your supplemental new drug application dated October 27, 2006, received October 31, 2006, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BiCNU® (carmustine) for Injection, 100 mg/vial.

We acknowledge receipt of your submissions dated April 18, June 8, and August 14, 2007. Your submission dated April 18, 2007, constituted a complete response to our February 27, 2007, action letter.

This supplemental new drug application provides for the following:

- Adding Luitpold Pharmaceuticals, Shirley, NY, as an alternative manufacturing and quality control and stability testing site for the alcohol diluent,
- Modifications to the method of manufacture of the diluent,
- Addition of a glass ampule as a primary container for the diluent,
- Modifications to the release specifications for the diluent,
- Changes to the package insert, the BiCNU® and Dehydrated Alcohol Injection container labels, and the combination pack carton,
- Modification to the approved market-life stability protocol for BiCNU®, and
- Addition of an alternate secondary packaging site for the BiCNU® combination pack.

We have completed our review of this 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, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert submitted on June 8 and amended on August 14, 2007). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved supplemental NDA 17-422/S-037."

## CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels and/or 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 supplemental NDA 17-422/S-037**." 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.

## LETTERS TO HEALTH CARE PROFESSIONALS

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

## 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 Susan Jenney, Regulatory Health Project Manager, at (301) 796-0062.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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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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Eric Duffy

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