DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA17-588/S-034

Bristol-Myers Squibb Company
Attention: Fred Frullo
Director Oncology Global Regulatory Sciences
PO Box 4000
Princeton, NJ 08543-4000

Dear Mr. Frullo:

Please refer to your supplemental new drug application S-034 dated July 27, 2006, received July 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CeeNu® (lomustine) Capsules.

Please also refer to your electronic mail correspondence of February 3, 2009 indicating agreement with FDA requested recommended revisions.

This "Changes Being Effected" supplemental new drug application provides for adding safe handling text to the **PRECAUTIONS: Information for Patients** and the **HOW SUPPLIED: Directions for the Pharmacists** sections as well as amending the storage statement to the USP standard definition in the **HOW SUPPLIED: Stability** section. Minor editorial changes were also included.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Submit 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 in content to the enclosed labeling text at the time of next printing. 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 supplement NDA 17-588/S-034".**

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

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

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 James M. Saunders, Regulatory Project Manager, at (301) 796-0621.

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 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/

Robert Justice

4/30/2009 06:02:16 PM