DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-588/S-031

Bristol-Myers Squibb Company
Attn: Joseph A. Linkewich, Pharm.D.
Director, U.S. Regulatory Liaison
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Dr. Linkewich:

Please refer to your supplemental new drug application dated December 12, 1996, received December 17, 1996, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for CeeNU® Lomustine (CCNU) Capsules.

This "Changes Being Effected" supplemental new drug application provides for new labeling to comply with the Final Rule for Specific Requirements on Content and Format of Labeling for Human Prescription drugs - Pediatric Use, as published in the Federal Register on December 13, 1994.

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 your December 12, 1996, submission.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted, December 12, 1996).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-588, S-031." Approval of this submission by FDA is not required before the labeling is used.

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 Amy Baird, Regulatory Project Manager, at (301) 594-5779.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

Richard Pazdur

12/20/02 12:48:43 PM