DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-452/S-001

Bristol-Myers Squibb Company
P.O. Box 4000
Princeton, NJ 08543-4000

Attention: Noemi C. Guma, Ph.D.
Group Manager, Global Regulatory Sciences, CMC

Dear Dr. Guma:

Please refer to your supplemental new drug application dated September 8, 2003, received September 9, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PARAPLATIN® (carboplatin aqueous solution) INJECTION.

We acknowledge receipt of your submission dated December 30, 2003.

We also acknowledge your submission dated July 31, 2003, received August 4, 2003, providing final printed labeling in response to our July 14, 2003, approval letter for NDA 20-452. The final printed labeling will be retained with your files as it is superseded by the September 9, 2003, draft labeling.

This supplemental new drug application provides for the following changes: A new 600 mg vial presentation; the addition of Bristol-Myers Squibb Latina, Italy facility as an alternate manufacturing, packaging, quality control, release and stability testing site; revised labeling from single dose vial to multidose vial; and a revised Market Life Stability Protocol to include the 600 mg vials and extend the study period to 24 months.

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 submitted labeling text and with the minor revision listed below.

> Evaluation of the draft carton and vial labels provided for the 600 mg presentation revealed that the color scheme of the 600 mg presentation is too similar to the color scheme of the 450 mg presentation. Please revise the color scheme of either the 450 mg or the 600 mg carton and vial labels in order to eliminate prescription filling errors.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert and immediate container and carton labels submitted September 8, 2003) with the addition of the revision above.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-452/S-001." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Christy Cottrell, Consumer Safety Officer, at (301) 594-5761.

Sincerely,

{See appended electronic signature page}

Rebecca Wood, Ph.D.
Chemistry Team Leader
Division of New Drug Chemistry I
Office of New Drug Chemistry
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/

Richard Lostritto

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