DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018057/S-080

SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company
Attention: Angela Glauberzon
Associate Director, Global Regulatory Sciences Mature Products
Bristol Myers Squibb Research & Development
P.O. Box 4000 (Mail Stop: D22-09)
Princeton, NJ 08543-4000

Dear Ms. Glauberzon:

Please refer to your Supplemental New Drug Application (sNDA) dated November 01, 2010 received November 01, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PLATINOL® (cisplatin for injection, USP).

This "Changes Being Effected" supplemental new drug application provides for revisions to:

1. WARNINGS section to include administration precautions for extravasation and administration site reactions
2. ADVERSE REACTIONS section to include updated information to subsection Other Events, and adding Leukoencephalopathy and Reversible Posterior Leukoencephalopathy Syndrome (RPLS) to subsection Neurotoxicity.
3. DOSAGE AND ADMINISTRATION section to add administration precaution
4. the end of the label to include the Manufacturing site (b) (4) new text added above the BMS Signature text indicating that PLATINOL will now be manufactured at a Non-BMS site; "Manufactured for:"

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to, except with the revisions listed/indicated, the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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 via publicly available labeling repositories.

Also within 14 days from the date of this letter, amend all pending supplemental applications for this NDA, including pending CBE supplements, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes with the revisions indicated above approved in this supplemental application.

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Lisa Skarupa, Regulatory Project Manager, at (301) 796-2219.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

AMNA IBRAHIM
08/26/2011