



NDA 018057/S-079

SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company
Attention: Beatrice Anduze-Faris, M.D.
Group Director, Mature Products, Global Regulatory Sciences
Bristol-Myers Squibb
P.O. Box 4000 (Mailstop D12-02)
Princeton, N.M. 08543-4000

Dear Dr. Anduze-Frais:

Please refer to your Supplemental New Drug Application (sNDA) dated April 25, 2007, received April 26, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PLATINOL®-AQ (cisplatin injection) and PLATINOL® (cisplatin for injection, USP).

We acknowledge receipt of your amendments dated May 7 and July 15, 2010.

This "Changes Being Effected" supplemental new drug application provides for the removal of the Bristol-Myers Squibb Oncology logo, and:

- Addition of safe handling statements to DOSAGE AND ADMINISTRATION: STABILITY Section;
- In DESCRIPTION Section, revision of product description to align with current FDA guidelines;
- Updating of the ADVERSE REACTIONS: Nephrotoxicity, Hematologic and Other Events subsections with new information;
- Addition of paragraph in the DOSAGE AND ADMINISTRATION: PREPARATION OF INTRAVENOUS SOLUTIONS Section advising to inspect visually for particulate matter;
- Updating of the REFERENCES Section
- Minor editorial changes were made to the package insert.

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}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-18057	SUPPL-79	BRISTOL MYERS CO	PLATINOL

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

/s/

ANTHONY J MURGO

09/02/2010

Anthony J. Murgo, MD signing for:
Robert L. Justice, M.D., M.S.