DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA022065/S-004/ S-005 **SUPPLEMENT APPROVAL**

Bristol-Myers Squibb Company
Attention: Catherine Burgess, Ph.D.
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492

Dear Dr. Burgess:

Please refer to your supplemental new drug applications. Submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for IXEMPRA Kit, (ixabepilone) for intravenous infusion.

Supplement	Letter date	Received date	Provides for	Your Amendments
022065/S-004	November 10, 2009	November 10, 2009	Updating section 7.1 of the package insert to include data on co-adminstration of ixabepilone with rifampicin	March 1, 2010 March 2, 2010 March 26, 2010 April 6, 2010 April 13, 2010
022065/S-005	January 15, 2010	January 15, 2010	Updating section 6.2 Postmarketing Experience in the Adverse sections of the package insert to include information on radiation recall	March 1, 2010 March 2, 2010 March 26, 2010 April 6, 2010 April 13, 2010

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 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., "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
Food and Drug Administration
Suite 12B-05
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 Alberta Davis-Warren, Regulatory Project Manager, at (301) 796-3908.

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(S):
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22065	SUPPL-5	BRISTOL MYERS SQUIBB CO	IXEMPRA
NDA-22065	SUPPL-4	BRISTOL MYERS SQUIBB CO	IXEMPRA

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

05/12/2010

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