DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022065/S-002/S-003 **SUPPLEMENT APPROVAL**

Bristol-Myers Squibb Company
Attention: Catherine Burgess, Ph.D.
Associate Director – Oncology, Global Regulatory Science
5 Research Parkway
Signature 91 Building, 3SIG-3019
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
22-065/S-002	December 12, 2008	December 12, 2008	Overall survival data from study CA163046	February 13, 2009 June 30, 2009 August 28, 2009 October 1, 2009
22-065/S-003	May 13, 2009	May 13, 2009	Updating Peripheral Neuropathy to Warnings and Precautions section of the package insert	June 30, 2009 August 28, 2009 October 1, 2009

We have completed our review of this 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, please submit 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) submitted October 1, 2009. For administrative purposes, please designate this submission, "**SPL for approved NDA 022065**."

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
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}

Ann T. Farrell, M.D.
Deputy Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure
Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22065	SUPPL-2	BRISTOL MYERS SQUIBB CO	IXEMPRA
NDA-22065	SUPPL-3	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/

ANN T FARRELL
10/02/2009