DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050794/S-023

SUPPLEMENT APPROVAL

Celgene Corporation
Attention: Penny Ng
Senior Manager, Regulatory Affairs
9900 West 109th Street, Suite 300
Overland Park, KS 66210

Dear Ms. Ng:

Please refer to your Supplemental New Drug Application (sNDA) dated November 8, 2011, received November 9, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vidaza® (azacitidine) for Injection

We acknowledge receipt of your amendments dated December 16, 2011 and January 20, 2012.

This "Changes Being Effected" supplemental new drug application provides for the addition of "tumor lysis syndrome," "injection site necrosis," and "Sweet's syndrome (acute febrile neutrophilic dermatosis)" to the Adverse Reaction – Postmarketing Experience section of the package insert (PI).

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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, contact Karen Bengtson, Regulatory Project Manager, at (301) 796-3338 or Karen.Bengtson@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Robert Kane, M.D.
Acting Deputy Director for Safety
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

ROBERT C KANE
01/24/2012