DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-794/S-011

Celgene Corporation
9900 West 109th Street, Suite 300
Overland Park, KS 66210

Attention: Ann Tanner, R.Ph., MPH, RAC
Director, Regulatory Affairs

Dear Ms. Tanner:

Please refer to your supplemental new drug application dated February 28, 2008, received February 28, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vidaza® (azacitidine) for Injection, single use vial, 100 mg.

We acknowledge receipt of your submissions dated February 28, 2008; April 11, 22, and 28, 2008; May 8, 2008; July 29, 2008, and August 13, 18, 19, and 20, 2008.

This supplemental new drug application provides revised labeling for the use of Vidaza® (azacitidine) for Injection, in patients with myelodysplastic syndrome (MDS) based on results from a randomized trial comparing subcutaneous azacitidine plus best supportive care versus conventional care regimens plus best supportive care.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 50-794/S-011**." Approval of this submission by FDA is not required before the labeling is used.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

We further remind you of the postmarketing study commitment made in your submission dated May 18, 2004:

> As azacitidine and its metabolites are primarily excreted by the kidneys, you have agreed to conduct a formal pharmacokinetics and safety study in patients with varying degrees of renal impairment. The results of this study will support dosing recommendations for this patient population especially during the first course of therapy. Dose proportionality should also be explored in this study.
>
> You have agreed to the following schedule:
>
> | | |
> |---|---|
> | Protocol Submission: | by August 2004 |
> | Study Start: | by November 2004 |
> | Final Report Submission: | by May 2006 |

Submit clinical protocols to your IND for this product. Submit non-clinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
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 Kim J. Robertson, Consumer Safety Officer, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

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

Enclosure (label)

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

/s/

Ramzi Dagher

8/20/2008 03:44:22 PM