DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021880/S-023

SUPPLEMENT APPROVAL

Celgene Corporation
Attention: Marion Ceruzzi, Ph.D.
Director, Regulatory Affairs
400 Connell Drive, Suite 7000
Berkeley Heights, NJ 07922

Dear Dr. Ceruzzi:

Please refer to your Supplemental New Drug Application (sNDA) dated June 30, 2010, received July 1, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for REVLIMID (lenalidomide) 2.5 mg, 5 mg, 10 mg, 15 mg, 25 mg Capsules.

We acknowledge receipt of your amendments dated August 17, September 30, November 19, and 24, December 10, 16, 17, 23, and 29; January 28, March 4, April 12, 19, and 26, June 24, October 5, and December 9, 2011.

The June 24, 2011, submission constituted a complete response to our April 22, 2011, action letter.

This "Prior Approval" supplemental new drug application provides for updates to the package insert based upon trials CC-5013-MDS-004 "A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, 3-Arm Study of the Efficacy and Safety of 2 Doses of Lenalidomide versus Placebo in Red Blood Cell (RBC) Transfusion-dependent Subjects with Low or Intermediate-1-risk Myelodysplastic Syndromes (MDS) Associated with a Deletion 5q[31] Cytogenetic Abnormality" and CC-5013-MDS-003 "A Multicenter, Single-Arm, Open-Label Study of the Safety and Efficacy of Lenalidomide Monotherapy in Red Blood Cell Transfusion-Dependent Subjects with Myelodysplastic Syndromes associated with a del (5q) Cytogenetic Abnormality." Also, this supplemental new drug application provides for the addition of a 2.5 mg capsule dosage strength.

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, 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).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the container labels submitted on June 30, 2010, for the 10 mg, 15 mg, and 25 mg labels and the June 24, 2011, submission for the 2.5 mg label except with the revisions listed below, as soon as they are available, but no more than 30 days after they are printed.

The proposed container label for the 2.5 mg strength introduces vulnerability that can lead to medication errors because the established name lacks prominence and the strength statement, 2.5 mg, is not adequately differentiated. We recommend the following:

1. As currently presented, placing the strength within a color block does not adequately distinguish this strength from the 25 mg strength. We recommend you delete the color block and add a box around the strength to clearly differentiate it from the 25 mg strength.

2. Revise the presentation of the established name such that it has as much prominence commensurate with the proprietary name in accordance with 21 CFR 201.10(g)(2). This may include increasing the space between the letters within the established name and increasing its font size.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you that there are postmarketing requirements listed in the June 29, 2006 approval letter that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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, call Amy Baird, Regulatory Project Manager, at (301) 796-4969.

Sincerely,

{See appended electronic signature page}

Edvardas Kaminskas, M.D.
Acting Deputy Director
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/

EDVARDAS KAMINSKAS
12/21/2011