DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204026/S-003

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Celgene Corporation
Attention: Emmanuel Gutierrez
Manager, Regulatory Affairs
400 Connell Drive
Suite 7000
Berkeley Heights, NJ 07922

Dear Mr. Gutierrez:

Please refer to your Supplemental New Drug Application (sNDA) dated September 13, 2013, received September 13, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pomalyst® (pomalidomide).

This "Prior Approval" supplemental new drug application provides for updates to the package insert based upon data from the study entitled "A Phase 1 Open-Label Study to Evaluate the Effect of CYP450 and P-gp Inhibition and Induction of the Pharmacokinetics of Pomalidomide (CC-4047) in Healthy Male Subjects." Also, the data submitted serves to address PMR 2006-2 and PMR 2006-6.

APPROVAL & LABELING

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 that includes labeling changes 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).

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 none of these criteria apply to your application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated September 13, 2013, containing the final reports for the following postmarketing requirements listed in the February 8, 2013 approval letter.

PMR 2006-2 Conduct a clinical trial, per FDA guidance [Drug Interaction Studies—Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations], to determine the effect of CYP3A induction, which may decrease drug exposure, on the PK of Pomalyst (pomalidomide).

Final Report Submission: 9/2013

PMR 2006-6 Conduct a clinical trial, per FDA guidance [Drug Interaction Studies—Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations], in order to determine the effect of CYP3A inhibition, which may increase drug exposure and thereby drug toxicity, on Pomalyst (pomalidomide) pharmacokinetics.

The timetable you submitted on February 6, 2013, states that you will conduct this trial according to the following schedule:

Final Protocol Submission: 9/2012 (completed)
Trial Completion: 11/2012 (completed)
Final Report Submission: 9/2013.

We have reviewed your submission and conclude that the above requirements were fulfilled.

We remind you that there are postmarketing requirements and postmarketing commitments listed in the February 8, 2013 approval letter that are still open.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

2138-1 To conduct a clinical trial, per FDA Guidance [Drug Interaction Studies-Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations], in order to determine the effects of a strong CYP1A2 inhibitor such as fluvoxamine on the PK of Pomalyst (pomalidomide). CYP1A2 inhibition may increase Pomalyst (pomalidomide) exposure.

The timetable you submitted on March 13, 2014, states that you will conduct this study according to the following schedule:

Final Protocol Submission:	08/2014
Study/Trial Completion:	02/2015
Final Report Submission:	12/2015

Submit clinical protocols to your IND 066188 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing 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/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled "**Postmarketing Commitment Protocol**," "**Postmarketing Commitment Final Report**," or "**Postmarketing Commitment Correspondence**."

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/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. 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}

Robert C. Kane, MD
Deputy Division 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
03/13/2014