DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204026/S-012
NDA 204026/S-014

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENTS AND POSTMARKETING COMMITMENTS

Celgene Corporation
Attention: Emmanuel Gutierrez, BS
Senior 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 December 30, 2015 to Supplement 012, received December 30, 2015, and March 25, 2016 to Supplement 014, received March 25, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for POMALYST® (pomalidomide) capsule; 1, 2, 3, and 4 mg.

Supplement 12 provides for revisions to the prescribing information (PI) for POMALYST related to the final study reports for the following post marketing requirements and commitments: PMR 2006-4, PMR 2006-7, PMC 2006-10, PMC 2138-1, and the pregnancy and lactation labeling final rule (PLLR) updates to the US Prescribing Information (USPI).

Supplement 14 provides for updates to the PI and fulfillment of PMR 2006-5: pooled analysis of subjects with relapsed or refractory Multiple Myeloma (RRMM) and impaired renal function from two clinical trials, CC-4047-MM-008 and CC-4047-MM-013.

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, Medication Guide), 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 REQUIREMENTS/COMMITMENTS

We have received your submissions dated September 30 and December 30, 2015; and March 25, 2016, containing the final reports for the following postmarketing requirements and postmarketing commitments listed in the February 8, 2013 and March 13, 2014 approval letters.

PMR 2006-4 Conduct a clinical trial, per FDA guidance [Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling], in patients with baseline hepatic impairment to determine the influence of hepatic impairment on the pharmacokinetics (PK) and safety of Pomalyst (pomalidomide).

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

Final Protocol Submission:	05/2013
Trial Completion:	05/2015
Final Report Submission:	02/2016

PMR 2006-5 Conduct a clinical trial, per FDA guidance [Pharmacokinetics in Patients with Impaired Renal Function--Study Design, Data Analysis, and Impact on Dosing and labeling, in patients with baseline renal impairment and those on chronic dialysis], to determine the influence of renal impairment on the PK and safety of Pomalyst (pomalidomide).

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

Final Protocol Submission:	05/2013
Trial Completion:	05/2015
Final Report Submission:	02/2016

PMR 2006-7 Conduct a food effect clinical trial, per FDA guidance [Food-effect Bioavailability and Fed Bioequivalence Studies], in order to determine the effect of food on the pharmacokinetics of Pomalyst (pomalidomide). The trial should be conducted in patients age > 60 years old using the commercial formulation of pomalidomide.

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

Final Protocol Submission:	03/2014
Trial Completion:	12/2014
Final Report Submission:	09/2015

PMC 2006-10 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 CYP1A2 inducer (such as montelukast) on the PK of Pomalyst (pomalidomide). CYP1A2 induction may decrease Pomalyst (pomalidomide) exposure and result in diminished efficacy.

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

Final Protocol Submission:	03/2014
Trial Completion:	12/2014
Final Report Submission:	09/2015

PMC-2138-1 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

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

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our Feb 8, 2013 and March 13, 2014 action letters.

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:

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

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

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 Laura Wall, Regulatory Project Manager, at (301) 796-2237.

Sincerely,

{See appended electronic signature page}

Ann T. Farrell, MD
Director
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
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/

ANN T FARRELL
06/30/2016