



NDA 204026/S-004

**SUPPLEMENT APPROVAL  
REMS MODIFICATION**

Celgene Corporation  
Attention: Marion Ceruzzi, PhD  
Senior Director, Regulatory Affairs  
400 Connell Drive, Suite 7000  
Connell Corporate Park  
Berkley Heights, NJ 07922

Dear Dr. Ceruzzi:

Please refer to your Supplemental New Drug Application (sNDA) dated March 13, 2014, received March 13, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for POMALYST<sup>®</sup> (pomalidomide) Capsules 1, 2, 3, and 4 mg.

We acknowledge receipt of your amendments dated July 10 and September 8, 2014.

This "Prior Approval" supplemental new drug application provides for proposed modifications to the approved risk evaluation and mitigation strategy (REMS) for POMALYST<sup>®</sup> (pomalidomide).

**APPROVAL**

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

**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

**RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS**

The REMS for POMALYST® (pomalidomide) was originally approved on February 8, 2013, and was last modified on November 15, 2013. The REMS consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS. Your proposed modifications to the REMS consist of the following:

1. Removal of the “Rules for Dispensing” section in the Education and Counseling Checklist for Pharmacies.
2. Update to the current International Statistical Classification of Diseases and Related Health Problems (ICD) classifications in the Patient Prescription Forms.

We remind you that section 505-1(f)(8) of FDCA prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

Your proposed modified REMS, submitted on July 10, 2014, and appended to this letter, is approved.

We also acknowledge the following changes to the REMS Supporting Document: The improvement of the REMS Pharmacy Portal interface and the Prescriber Portal interface and the revised pharmacist survey protocol and revised Adult Female of Reproductive Potential (AFRP) contraception choice survey protocol.

The timetable for submission of assessments of the REMS will remain the same as that approved on February 8, 2013.

There are no changes to the REMS assessment plan described in our November 15, 2013 letter.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

**NDA 204026 REMS CORRESPONDENCE**  
**(insert concise description of content in bold capital letters, e.g.,**

**UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT  
METHODOLOGY)**

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

**NDA 204026 REMS ASSESSMENT**

**NEW SUPPLEMENT FOR NDA 204026  
PROPOSED REMS MODIFICATION**

**NEW SUPPLEMENT (NEW INDICATION FOR USE)  
FOR NDA 204026  
REMS ASSESSMENT  
PROPOSED REMS MODIFICATION (if included)**

If you do not submit electronically, please send 5 copies of REMS-related submissions.

**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) 796-4949.

Sincerely,

*{See appended electronic signature page}*

Robert C. Kane, MD  
Deputy Director of Safety  
Division of Hematology Products  
Office of Hematology and Oncology Products  
Center for Drug Evaluation and Research

ENCLOSURE:  
REMS

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ROBERT C KANE  
09/12/2014