DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020785/S-054

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 THALOMID® (thalidomide) Capsules 50, 100, 150, and 200 mg.

We acknowledge receipt of your amendments dated July 11 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 THALOMID® (thalidomide).

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 THALOMID® (thalidomide) was originally approved on August 3, 2010, a REMS modification was approved on February 8, 2013, and the REMS 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 11, 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 August 3, 2010.

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 020785 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 020785 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 020785
PROPOSED REMS MODIFICATION

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 020785
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(S):
REMS

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
09/12/2014