DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-880/S-006
NDA 21-880/S-016
NDA 21-880/S-017

Celgene Corporation
Attention: Michael Faletto, Ph.D.
Senior Director, Regulatory Affairs, Oncology
86 Morris Avenue
Summit, New Jersey 07901

Dear Dr. Faletto:

Please refer to your supplemental new drug applications S-006 dated April 30, 2007 (received May 1, 2007), S-016 dated December 8, 2008 (received December 12, 2008), and S-017 dated December 22, 2008 (received December 24, 2008) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Revlimid® (lenalidomide) Capsules.

We also acknowledge receipt of your submissions dated July 27, December 28, 2007; March 21, June 9, September 2, and October 23 (electronic), 2008.

SLR-006 provides for revisions to the package insert. Based on the results of the pharmacokinetic study in patients with renal impairment, lenalidomide starting dose adjustments are recommended for patients with CLcr < 60 mL/min.

SLR-016 provides a revised package insert.

SLR-017 provides for revisions to the package insert to clarify the starting dose adjustment in patients with moderate or severe renal impairment and in patients on dialysis.

We have completed the review of these applications, as amended. These applications are approved, effective on the date of this letter, for use in the agreed-upon labeling text.

Include content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html.

If you have any questions, call Carl Huntley, Regulatory Project Manager, at (301) 796-1372.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Division Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure:

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Justice
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