DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-785/S-032

Celgene Corporation
Attention: William Woolever
Director, Regulatory Affairs
86 Morris Avenue
Summit, New Jersey 07901

Dear Mr. Woolever:

Please refer to your supplemental new drug application dated August 31, 2006, received September 1, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thalomid® (thalidomide) capsules, 50 mg, 100 mg, 150 mg, and 200 mg.

Please also refer to your submission dated November 21, 2006.

This supplemental new drug application provides for manufacture of the additional dosage presentation of 150 mg capsules.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert and patient package insert) submitted November 21, 2006, blister cards and carton labels submitted August 31, 2006.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-785/S-032**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Carl Huntley, Regulatory Project Manager, at (301) 796-1372.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief, Branch VIII
Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosures

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

/s/

Hasmukh Patel

1/10/2007 02:19:54 PM