DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-785/S-025, S-026

Celgene Corporation
Attention: William R. Woolever
Director, Regulatory Affairs
7 Powder Horn Drive
Warren, NJ 07059

Dear Mr. Woolever:

Please refer to your supplemental new drug application (S-025) dated and received September 5, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thalomid® (thalidomide) Tablets, 50 mg, 100 mg, 200 mg.

We acknowledge receipt of your submissions for S-025 dated March 1 and March 3, 2004.

This supplemental new drug application provides for the revision of the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.®) Informed Consent Forms and the S.T.E.P.S.® IVR Surveys. As you provided in your submission of March 1, 2004, the "Informed Consent Form" will now be designated as the "Patient-Physician Agreement Form."

Please refer also to your supplemental new drug application (S-026) dated and received December 19, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thalomid® (thalidomide) Tablets, 50 mg, 100 mg, 200 mg.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the package insert (additions are double underlined and deletions are ~~strikethrough~~):

ADVERSE REACTIONS

Other Adverse Events Observed in Post-Marketing Use

- ***"Digestive System;*** Intestinal perforation" was added to this subsection.

- "Tumor lysis syndrome" was added to the ***Metabolic and Endocrine*** adverse events as follows:

> ***Metabolic and Endocrine:*** Electrolyte imbalance including hypercalcemia or hypocalcemia, hyperkalemia and hypokalemia, hyponatremia, hypothyroidism, and increased alkaline phosphatase, tumor lysis syndrome.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is

safe and effective for use as recommended in the agreed upon labeling text (enclosed). Accordingly, the supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted December 27, 2003).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated **"FPL for approved supplement NDA 20-785/S-026."** Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Robin Anderson, R.N., M.B.A., Labeling Reviewer, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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

/s/

Renata Albrecht
3/5/04 03:13:17 PM