DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-785/S-020 and S-021

Celgene Corporation
Attention: Steve Thomas, Ph.D.
Vice President, Project Management and Regulatory Affairs
7 Powder Horn Drive
Warren, NJ 07059

Dear Dr. Thomas:

Please refer to your supplemental new drug application (S-020) dated and received March 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thalomid® (thalidomide) Capsules.

This supplemental new drug application (S-020) provides for the following:

- A change to a higher potency blend formulation, replacement of the current marketed 50-mg capsule with a new 50-mg capsule formulation, and the introduction of a 100-mg and a 200-mg capsule.
- Revised cartons, blister pack cards, and package insert (**DESCRIPTION** and **HOW SUPPLIED** sections) to reflect the new formulation and addition of the 100-mg and 200-mg capsules.

Please also refer to your supplemental new drug application (S-021) dated and received May 24, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thalomid® (thalidomide) Capsules.

This supplemental new drug application (S-021) provides for the following:

- Changes to the labeling to comply with Enhanced S.T.E.P.S. (System for Thalidomide Education and Prescribing Safety).
- Revised cartons, blister pack cards, and package insert to reflect additional labeling revisions for the new formulation and addition of the 100-mg and 200-mg capsules.

We acknowledge receipt of your submissions dated December 6, December 10, December 19, and December 20, 2002 as well as January 3 and January 9, 2003.

Your submission of January 16, 2003, constituted a complete response to our December 6, 2002 action letter.

We have completed the review of these 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. Accordingly, these applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert submitted May 24, 2002) and to the submitted labeling (carton labels submitted January 3, 2003, and blister pack labels submitted January 16, 2003).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDAs (January 1999). For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 20-785/S-020 and NDA 20-785/S-021." Approval of these submissions 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 Practitioner" 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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Matthew A. Bacho, Regulatory Project Manager, 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 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
1/17/03 03:59:16 PM
NDA 20-785/S-020 and S-021