DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

May 4, 2005

Michael E. Cole
Robert Deichert
Assistant Attorneys General
55 Elm Street, P.O. Box 120
Hartford, CT 06141-0120

FILE COPY

Dear Messrs. Cole and Deichert:

Your petition requesting the Food and Drug Administration to require Celgene Corporation to revise the labeling of Thalomid Capsules to strengthen warning of the potential for serious adverse events when prescribed in combination with other cancer treatment therapies was received by this office on 05/04/2005. It was assigned docket number 2005P-0167/CP 1 and it was filed on 05/04/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0167

ACK1