



Food and Drug Administration  
Rockville, MD 20857

**FILE COPY**

August 11, 2005

Geoffrey Allan, Ph.D.  
President & Chief Executive Officer  
Insmed Incorporated  
P.O. Box 2400  
Glen Allen, VA 23058-2400

Dear Dr. Allan:

Your petition requesting the Food and Drug Administration to immediately deny approval of the NDA for INCRELEX was received by this office on 08/11/2005. It was assigned docket number 2005P-0322/CP 1 and it was filed on 08/11/2005. 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-0322

ACK 1