



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

April 10, 2006

FILE COPY

Marlene Keeling, President
Chemically Associated Neurological Disorders
P.O. Box 682633
Houston, TX 77268-2633

Dear Ms. Keeling:

Your petition requesting the Food and Drug Administration to stay the current approvable letter with conditions of any and all Premarket Applications for silicone gel-filled breast implants (SGFBI's) for an indefinite time due to the 2006 peer-reviewed published research finding significant levels of ionized platinum are released after implantation from second and third generation SGFBI's, was received by this office on 04/07/2006. It was assigned docket number 2006P-0151/PSA 1 and it was filed on 04/10/2006. 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

2006P-0151

ACK 1