



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 7, 2006

Peter Lurie, MD
Nicholas Stine
Sidney M. Wolfe, MD
Public Citizen
1600 20th Street
Washington, District of Columbia 20009

FILE COPY

Dear Dr. Lurie:

Your petition requesting the Food and Drug Administration to revoke FDA's prior approval of vagus nerve stimulation (VNS) for management of treatment-resistant depression (TRD), was received by this office on 09/06/2006. It was assigned docket number 2006P-0370/CP1 and it was filed on 09/06/2006. 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,

Jennie C. Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

2006P.0370

ACK 1