DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Peter Lurie, M.D., M.P.H.
Deputy Director
Public Citizen
1600 20th Street NW
Washington, DC 20009

MAR 0 2 2007

Re: Citizen Petition – Docket Number 2006P-0370/CP1
Dated: September 6, 2006
Received: September 6, 2006

Dear Dr. Lurie:

This is an interim response to your petition dated September 6, 2006, which was filed by the Food and Drug Administration (FDA) on September 6, 2006. In your petition, you asked FDA to reverse the approval of the vagus nerve stimulation (VNS) device for the management of treatment-resistant depression (TRD) because, according to your petition, "the device has not demonstrated a 'reasonable assurance that the device is safe and effective,' the standard under the law, 21 CFR 860.7(4)(c)(1)."

We are still in the process of reviewing your concerns, and are unable to issue a final response to you at this time.

If you have any questions about this interim response, please contact Ruth Fischer of our Regulations Staff at (240) 276-2349.

Sincerely yours,

Linda S. Kahan
Deputy Director
Center for Devices and
Radiological Health