

February 1, 2005

**Editorial: FDA's Warning Letter to Cyberonics Regarding Vagus Nerve Stimulator and Good Manufacturing Practice Requirements**

[http://www.fda.gov/foi/warning\\_letters/g5129d.htm](http://www.fda.gov/foi/warning_letters/g5129d.htm)

Orrin Devinsky, M.D.  
NYU Epilepsy Center

After an inspection of the manufacturing facility in Texas, the FDA recently notified Cyberonics there were problems with their production of vagus nerve stimulators (VNS). They raised concerns about the methods, the facilities and or controls used for their manufacturing, packing, storage, or installation stating, "in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) Regulation for medical devices, as specified in Title 21, Code of Federal Regulation (CFR). Part 820."

It is difficult to assess the seriousness of this notification. The issues raised by the FDA could reflect failure on the part of Cyberonics to provide complete documentation and investigation of potential or definite problems with the vagus nerve stimulator. In other words, the VNS implanted does not work properly in everyone due to technical problems with the leads, unexpected short battery life, or other problems. It is therefore important to investigate and document the causes of why the implantation was unsuccessful.

To read the full editorial please go to:  
[http://www.epilepsy.com/articles/ar\\_1107185385.html](http://www.epilepsy.com/articles/ar_1107185385.html)

**Stories from Health Care Professionals:**

[http://professionals.epilepsy.com/page/doctor\\_stories.html](http://professionals.epilepsy.com/page/doctor_stories.html)

In an effort to bring to light the often heart-wrenching nature of working with patients with epilepsy, we have created the "Stories from Professionals" section. If you are a health care professional working with patients with epilepsy and you would like to share your story please email your submission to: Epilepsy.com Editor, [jenna@epilepsyproject.org](mailto:jenna@epilepsyproject.org)

**Visit Our Library:**

<http://professionals.epilepsy.com/page/doclib.html>

At epilepsy.com/professionals our goal is to offer a comprehensive library of materials available for download that will help healthcare professionals better treat those living with epilepsy. As such, we are excited to announce the expansion of the Document Library. Be sure to visit the Document Library for the latest information regarding vocational rehabilitation, quality-of-life and new management strategies for the treatment of status epilepticus. If you have ideas or suggestions for additions to the Document Library please email [jenna@epilepsyproject.org](mailto:jenna@epilepsyproject.org)

**Stay Tuned:**

[www.epilepsy.com/professionals](http://www.epilepsy.com/professionals)

Upcoming features on epilepsy.com/professionals include:

- The latest research on treatment options for seizure emergencies.
- A more comprehensive and user friendly clinical trials area, providing integrated clinical trials in all 50 states and around the globe.

## Mark Your Calendar:

Upcoming epilepsy-related conferences and symposiums include:

- February 23-February 26, 2005  
Third Mediterranean Neuroscience Congress and Eighth Etnean Epilepsy Workshop  
Catania (Sicily)
- March 17-March 19, 2005  
AntiEpileptic Drug Trials VIII  
Key Biscayne, FL
- April 09-April 16, 2005  
American Academy of Neurology Meeting  
Miami Beach, FL
- December 2-December 6, 2005  
American Epilepsy Society 59th Annual Meeting  
Washington, DC

For a complete listing go to: <http://professionals.epilepsy.com/page/conference.ph>