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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

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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

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<http://professionals.epilepsy.com>

At epilepsy.com we are continually striving to provide our users with the most comprehensive and current epilepsy information. As such, we are excited to announce the launch of our new website geared towards healthcare professionals. In conjunction with our existing site, we now bring the latest research findings and information in epilepsy treatment and diagnosis to both patients and clinicians. We believe that the knowledge and experience of the epilepsy experts who contribute to epilepsy.com/professionals, as well as their informed opinions, will assist clinicians when caring for patients facing newly diagnosed epilepsy, as well as patients struggling with epilepsy that has resisted the usual treatments. Please feel free to share this information with your physician or neurologist on your next visit.

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Poetry Corner:

http://www.epilepsy.com/epilepsy/poetry_corner.html

The ability to paint images with words is an incredible gift; a gift that many of our visitors want to share with the epilepsy community. In response to overwhelming requests for a space to share their remarkable gift, we have recently added the Poetry Corner. We would like to thank all of you who submitted your poetry and invite everyone to visit the Corner and read the remarkable works of our contributors. We are always accepting poetry submissions, so if you are a writer and a person with epilepsy please send your submissions to Epilepsy.com Editor: jenna@epilepsyproject.org.

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