When the Federal Drug Administration (FDA) issues a "Class 1 recall" of a device, service, or medication being offered the public, that's serious. It means that they believe the item has a reasonable probability that it will cause "adverse health consequences or death."

Now, I don't think it took concentrated investigative powers of perception for the Administration to determine that anything called a "Vibrational Integrated Bio-photonic Energizer" - made by manufacturer VIBE Technologies of Greeley, Colorado, or the "HLX8" device made by Nebion of Los Angeles, California, might not perform as advertised. The VIBE device is sold to treat cancer, infections, and depression, while the HLX8 claims to treat: cancer - breast, bone, lung, and pancreatic, carpel tunnel syndrome, migraine, premenstrual syndrome, rheumatoid arthritis, shingles, sports injuries, sprains, and ruptured discs - an obviously wider range of ailments. Recalls were issued on both company's products.

Dr. Daniel G. Schultz, director of the FDA's Center for Devices and Radiological Health, said:

These recalls underscore the importance of taking action against manufacturers who make false medical claims for their devices... One of the FDA's primary responsibilities is protecting consumers from harm that can be caused by manufacturers who try to sidestep the approval and clearance process.

The FDA investigation of the VIBE claims began back in November of 2007, when they found that the company had not obtained FDA marketing approval or clearance for their device. On April 11, 2008, they issued a warning letter to them, and also cited the company for deviations from the Good Manufacturing Practice/Quality System regulations. More than a year passed before the FDA finally decided to close them down, while customers continued to purchase and use the product.

The FDA was aware of information suggesting that the VIBE device was used for cancer patients, and death occurred to one patient who used it, though the FDA has not verified that there is an association between that death and the device.

In June of 2008, the FDA inspected Nebion, and found that the company had not obtained FDA marketing approval or clearance for the HLX8 device, and they also uncovered substantial deviations from the Good Manufacturing Practice/Quality System regulation. As a result, Nebion recalled eight HLX8 devices, and notified their customers to stop using the devices immediately and to contact Nebion for their retrieval. The FDA has not received any reports of injuries or deaths linked to the HLX8 device.

Under federal law, any product that claims to diagnose a disease or condition, to cure, mitigate, treat or prevent a disease, or that is intended to affect the structure or function of the human body, is a product subject to the jurisdiction of the FDA and may require their approval or clearance prior to marketing it. Premarket approval is the most stringent type of FDA device review and is for devices with a high level of risk, such as those that support or sustain human life. Regular FDA clearance is for lower risk devices or materials that are shown to be as safe and effective as similar devices or materials already on the market.

In summary, neither VIBE Technologies nor Nebion were able to show the FDA that their devices are safe and/or effective at curing or treating diseases, as they had claimed, and they have been withdrawn from sale.