

Natural Therapies Certification Board News

May 20, 2008

FDA Meeting

Former NTCB president, Dr. John Gilbert and his attorney spoke with John's contacts at the FDA on May 20th and report as follows:

"The FDA ban on importing the EPFX to the US from Hungary is still in effect. The FDA has not banned and does not plan to ban the use, sale or purchase of the EPFX in the USA. The ban is only for importation of the EPFX from Hungary.

"The EPFX manufacturer is implementing FDA requirements to remove all claims other than relaxation for stress reduction from their web site, brochures and other pamphlets and correspondence. The EPFX manufacturer is also removing all claims of diagnosing anything with the EPFX by calling the EPFX an EDS device. The EPFX is legally a biofeedback device to be used only for relaxation to reduce stress in both the USA and Canada."

Additionally, Dr. Gilbert and his attorney have addressed the rumor that NTCB and BCIA certification of EPFX practitioners is illegal in the USA and Canada:

"NTCB and BCIA certification of EPFX practitioners is absolutely legal in the USA and Canada. Both the FDA and Health Canada require EPFX operators be licensed in their state or province or be certified by an established and accredited certification board. NTCB is established and accredited as a certification board operating in the USA and Canada."

Notes from Regional Director - Jake Cunningham

Thanks to Rocky Mountain Regional Director, Jake Cunningham for providing this information. You may contact him directly at: jake@whitedovehealing.com

Q: What is the legality of this device? Is it legal?

A: Yes it is.

Q: Can practitioners be jailed for using the EPFX device?

A: No, FDA can be an issuer of a notice to cease and desist only.

Q: Can the FDA confiscate the EPFX Device?

A: No, they cannot confiscate the devices.

Q: Is it now/still legal to sell the EPFX device?

A: Yes, nothing is in place to limit the sale of this device at

this time.

Q: How long will the current EPTX inventory last?

A: We now have a 6 month supply here in the US. We are looking to soon manufacture them in the US.

Q: Should we with-hold this FDA issue from prospective buyers?

A: No, but make sure you do not mis-represent what the issue is. No deceit = no problems and good relationships. Stay within statements of fact about biofeedback.

Q: Can we take the device in and out of the US without confiscation concerns?

A: Yes, you simply say, "This is my personal device, I am taking it in and out of the country for my personal use."... In this case, our lawyer suggests to bring your sales receipt as well as taking a picture of yourself in front of your home address with a newspaper showing the date of the newspaper clearly...this may not be necessary however.

Q:What is the status of the CAP (Corrective Action Plan), has it been agreed to?

A: The "CAP" is not all completed meaning the FDA has not yet responded. It is not unusual to not respond right away in an ongoing investigation. The FDA makes the call. They make "risk based decisions", for example, "Dangerous Devices". If they determine the device to be a "Dangerous Device" they would take swift actions. If they determine there is no public threat issues, they take longer to respond. We are not considered a "High Risk" to the general population

Q: Have we taken legal action against the Seattle Times and their misleading reporting?

A: Not yet, we need the import alert lifted and no charges after the investigation, then we ask for a retraction and correction of facts. The Seattle Times newspaper currently only has 1/3 of the Seattle readership and is not the leading newspaper. News that they are currently bankrupt and going out of business is the latest on their status. We have a recent lead within the #1 paper to do a positive story in the near future.

Q: What does an "Import Alert" mean?

A: An "Import Alert" does not mean you/we have done anything wrong. An alert can be imposed for many reasons. many registered and approved devices have had an "Importation Alert" at one time or another. Many times it is a paperwork error.

Q: How do we respond to suspicious calls asking, " do you cure this?" "Do you heal this?" Are we on a "FDA Watch list?"

A. Treat all calls as if they could be an agent. Not to worry though, just stay within your scope. Talk only about stress related to their "Dis-ease". Stick to stress reduction and management scripts related to general health. Check your literature for verbiage.

Q: What language can we use to explain the device?

A: Whatever is in the "510k" original registration. Above and beyond that is not OK. The key words are: "Specific, Indicated and Intended Use" ... so stay within these "510K" wordings.

Q: What is a "510K"?

A: it is alike a petition saying, "We have a device that we feel is equivalent to other registered/approved devices and we would like to market it." "Thus if we are the same as other registered devices we are given a 510K registration." Reviewers of 510k's attempt to prove equivalence or "same as" the predicated devices. They compare the 2 devices... ours and others. This is done by a scientific research team.

Q: How is our is our device classified?

A: The EPFX has attained "market clearance" by proving "equivalence", meaning it is equivalent to other biofeedback devices. There are 3 classes of medical devices: class 1's are things like tongue suppressors, class 2's are in the middle of the classifications like the EPFX = not harmful, like most devices. class 3's are things like pacemakers, kidney dialysis machines etc. our EPFX device is equivalent to other non-life-threatening devices.

Q: Can the FDA revoke a device registration?

A: They can, but this has been very infrequent. it is a very rare process and takes many steps to go through. Our experienced law team has not seen any revocations that he knows about. The only way the FDA can revoke a registration is if the applicant blatantly lied on the 510K application regarding equivalence.

Q: What about the use of the device with animals?

A: Remember that the FDA regulates the use of the device by regulating the manufacturer via the 510K. QX LTD. would have to prove that the EPFX actually reduces stress in animals, for exp. Let's say someone advertised that is cured cancer... the FDA and maybe even the FTC may write you very serious and troubling letter. And in this case, you are more likely to run into trouble with the Vet. Board of the state you are in. All/any claims may get you in trouble because all claims need scientific evidence of their validity. The veterinarians may claim they have a corner on the practice of medicine on animals.

Q: What type of legal team do we have to assist us if need be?

A: No need if we stay within the biofeedback boundaries. Yes, The Quantum Alliance team is here to help, yet is best to secure your own council. But remember, they are focused on the manufacturer in Budapest.

Q: What about a legal defense fund?

A: This is a great idea. And after our meeting at this years Congress of Masters it may very well be a reality. For now, you may want to put monies away monthly as an individual and retain someone now as a proactive move. Having the entire QA family create a trust fund would be the most powerful move as strength is always best developed in numbers. Authorities fight battles of attraction until

people give up out of fatigue via lack of time, energy and funds. A defense fund might be the answer as it could also be a tax deduction for us all as well.

*NOTE: **BANA** (<http://biofeedbackassociation.com>) offers its members liability, malpractice, arbitration coverage and more. For more information, please call Sara Greer, Executive Director at 800-985-0819 or visit them on their website. -- Jackie Olsen, Exec. Dir., NTCB*

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