

## **FDA Warning Letter: VanderVeer Center**

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December 2010

**Summary:** In November 2010, the FDA posted a warning letter to the VanderVeer Center regarding its website's description of the LipoDissolve product. What's unusual and noteworthy here is that the VanderVeer Center is not the drug manufacturer, but rather a provider of the treatment. Even so, the FDA states that the website offers unsubstantiated safety and efficacy claims, and the FDA also calls out the misbranding of the product. Health providers can benefit from knowing about this letter and ensuring that all promotional copy for drugs adheres to FDA guidelines.

### **Key Information**

In November 2010, the FDA issued a warning letter to the VanderVeer Center, a body enhancement center located in Portland, Oregon. The center offers medical procedures such as medical peels, Botox injections and mesotherapy treatments. The warning letter dealt with the misbranding of the LipoDissolve product, also referred to as meso-lipotherapy, on the center's site.

The center's website states that the LipoDissolve products are used for "spot fat reduction, cellulite reduction... scar revision... and the reduction of wrinkles" and also claims that "meso-lipotherapy has also proven effective for the non-surgical treatment of lipomas." As such, the LipoDissolve products are intended to treat disease in humans and affect the body's structure or function. Under FDA guidelines, this requires that they be labeled as drugs. Additionally, because the method of use for these products is only recommended under the supervision of a practitioner licensed by law, these products must be labeled as prescription drugs.

The efficacy and safety claims about LipoDissolve on the VanderVeer Center's site are also unsubstantiated. The page contains the following statements regarding the drug's efficacy, none of which are supported by any evidence:

- "Meso-lipotherapy has also proven effective for the non-surgical treatment of lipomas."
- "Meso-Lipotherapy is revolutionizing facial rejuvenation by offering the only nonsurgical treatment available for treating facial fat deposits."
- "Meso-lipotherapy is a cutting edge alternative to liposuction, plastic surgery and other invasive cosmetic procedures."

Regarding safety, the site makes several claims that imply that the LipoDissolve products have been proven safe; however, subcutaneous phosphatidylcholine has not been approved by the FDA for treatment of any conditions in the United States.

### **Implications and Action Items**

Although it is usually drug companies or manufacturers who receive FDA warnings for mislabeled drugs, the VanderVeer Center's case is illustrative of the fact that the facility offering a treatment bears equal responsibility for ensuring that drugs are correctly labeled and accompanied by correct safety and usage indications. While many health organizations hasten to offer the newest health treatments to patients, it is important to carefully vet all treatments to ensure that they are in accordance with FDA guidelines. Other organizations can learn from the VanderVeer Center by taking note of the following directives:

- **Ensure** that descriptive copy online and in brochures, and all promotional material, correctly classifies and labels drugs in conjunction with FDA guidelines.
- **Confirm** that all product claims about safety and efficacy are backed by clinical evidence and that the evidence is readily available and accessible.
- **Tread carefully** when prescribing off-label usage for a drug. Although physicians often prescribe drugs off-label, they should not be promoting or advertising uses for which a drug has not been approved.

**For more information on the warning letter, visit the FDA's website at: <http://bit.ly/8z97kM>. To see the VanderVeer Center's site, go to: <http://www.vanderveercenter.com/>.**