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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 7 2008

Warning Letter

Via Federal Express

William F. Gaunitz
Founder
Gaunitz Hair Sciences, LLC
7170 E McDonald Drive
Building 200, Suite 4
Scottsdale Arizona 85253

RE: THL-1™ Handheld Laser

Dear Mr. Gaunitz:

The Food and Drug Administration (FDA) has learned that your firm is marketing the THL-1™ Handheld Laser in the United States (U.S.) without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

The THL-1™ Handheld Laser is a device within the meaning of section 201(h) of the Act because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body. The Act requires that manufacturers of devices that are not exempt obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that new devices are shown to be both safe and effectives or substantially equivalent to other devices already legally marketed in the country for which approval is not required.

On August 5, 2008, the Office of Compliance (OC) in the Center for Devices and Radiological Health (CDRH) reviewed your websites, located at http://gaunitzlaser.com and http://www.hairgrowthcenters.com. Your websites describe the THL-1 laser as a "healing laser" that is intended to be used to grow hair by healing the scalp, allowing hair follicle recovery, and converting light energy into cellular energy. Your websites also suggest that your device is intended for use in the treatment of various diseases, such as acne, diabetic neuropathy, and wound healing.

For Example,

1. Your webpage located at http://gaunitzlaser.com/pages.php?pageid=31 states:
    - "What does the THL-1™ laser do? Low level laser therapy is proven to stimulate an accelerated healing response in the area of living tissue that is being treated. LLLT has been clinically proven by the FDA and used to treat:
        - Inflammation and scarring–even that caused by previous hair transplants.
        - Burns– accelerate the healing process of damaged tissue.
        - Acne– reduce scarring caused by acne.
        - Arthritis– alleviate pain and inflammation.

  - Diabetic Neuropathy– accelerates healing and can save appendages from amputation.
  - Wound healing– promotes rapid recovery. Used by plastic surgeons pre-operatively and has been shown to reduce bruising, scarring and inflammation."
- "The THL-1™ Handheld Laser is the first handheld hair growth laser of its kind."

2. Your webpage located at http://gaunitzlaser.com/product.php?productid=16137&cat=3&page=1 states:
   - "The cool, healing light of the THL-1™ laser penetrates the skin, improving circulation, increasing cell metabolism, reducing inflammation and promoting pain relief and rapid wound healing."
   - "Until now the biggest block in regrowing substantial amounts of hair was the body's inability to regenerate lost tissue. The THL-1™ maximizes the body's full growth potential by converting light energy into usable cellular energy."

3. Your webpage located at http://gaunitzlaser.com/pages.php?pageid=29 identifies a five (5) step treatment program that includes "Step 4: Treat" which includes a 5% Minoxidil solution and "Step 5: Healing Laser" which is the THL-1™ laser.

4. Your webpage located at http://www.hairgrowthcenters.com promotes the THL-1™ as part of the "Gaunitz Elite Hair Regeneration programs," which "promote a healthful scalp and hair as well as treat the body for the removal of toxins and improved system function." This site provides a link to the website www.gaunitzlaser.com.

A review of our records reveals that you have not obtained marketing approval or clearance before you began offering your product for sale, which is a violation of the law. Specifically, the THL-1™ Handheld Laser is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). The device is also misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by sections 510(k) of the Act, 21 U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

You should take prompt action to correct these violation(s). Failure to promptly correct these violation(s) may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and /or civil money penalties. Also, Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please submit a written response to this letter within 15 working days from the date you receive this letter, describing what steps you have taken to correct the problem and explaining how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response or any questions you may have to Thomas C. Knott at the Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, and facsimile at 240-276-0114.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your labeling and promotional materials for THL-1™ Handheld Laser comply with each applicable requirement of the Act and FDA implementing regulations. You should also understand that there are many FDA requirements pertaining to the manufacture and marketing of devices. This letter pertains only to the issue of premarket review for your device and does not necessarily address other violations you have under the law.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health