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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER

NWE-10-08W

Certified Mail

RETURN RECEIPT REQUESTED

March 21, 2008

Mr. Neil Camera, President
Laser Therapeutics, Inc
101 Waterside Drive
Centerville, Massachusetts 02632

Dear Mr. Camera:

The Food and Drug Administration (FDA) has learned that your firm is marketing the Softlaser under the trade names of Beurer, Etrans, and Vitalmed in the United States (U.S.) without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Under section 201(h) of the Act, the Softlaser, a low level laser therapy device, is a device 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, 21 U.S.C. 321(h). 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 effective or substantially equivalent to other devices already legally marketed in this country for which approval is not required.

Specifically, the "Guidelines for Use of the SOFTLASER" that accompanies your product includes, but is not limited to, instructions for the treatment of diseases such as acne, eczema/dermatitis, herpes/cold sores, psoriasis, ulcers, blisters/chapped skin, pressure sores, burns, aphthous ulcers, gingivitis, sinusitis, rhinitis, pain, tendonitis, and inflammations. Your labeling seeks to avoid making claims for medical use in the United States by stating that such treatments are designated as "Non-US Conditions."

effectively characterizes the treatment claims as, for example, not applying to U.S. conditions, is not a viable alternative because neither the disclaimer nor the qualifying language can rectify the message conveyed by the treatment claims. The use of such treatment claims in the labeling, even with the attempt at a disclaimer, is evidence of intended use. Thus, these treatment regimens establish these intended device uses for your device.

Further, on November 5, 2007, your website, www.lasertherapy.us, included new intended uses for the Softlaser. For example, the website makes medical claims which include, but are not limited to:

"While we can make no medical claims in the U.S., clinical trials in Europe have proven the Softlaser to be highly effective as part of a treatment regime for conditions such as: Acne• Bruising• Ulcers Eczema/Dermatitis• Psoriasis• Herpes/Cold Sore• Pressure Sores• Sprains• Wrinkles/Spider Veins/Blisters/Chapped Skin• Plantar Faciitis Burns• Wrinkles• Spider Veins• Tennis Elbow• Pain Relief• Tendinitis• Arthritis• Gingivitis• Dental Ulcer• Sinusitis/Rhinitis• Stimulation of acupuncture points"

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 Softlaser 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 devices are 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 devices into commercial distribution, as required by section 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.

In addition, laser products and medical lasers are subject to other regulatory requirements, including those in the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J. You have failed to comply with 21 CFR 1010.3 because the Softlaser lacks an identification label giving the manufacturing location and date of manufacture. In addition, you have failed to comply with 21 CFR 1002.13 because the Center for Devices and Radiological Health, FDA, has not received an Annual Report for the year from July 1, 2006, through June 30, 2007.

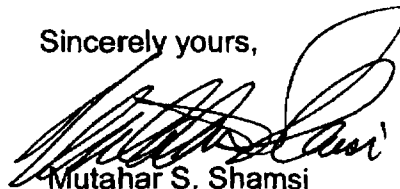
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You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited 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 let this office know in writing what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter. We also ask that you explain 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: Amber Wardwell, Compliance Officer, New England District Office, 1 Montvale Ave, 4th Floor, Stoneham, MA 02180.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of devices. This letter does not necessarily address all other obligations you have under the law for your device.

Sincerely yours,



Mutahar S. Shamsi
Acting District Director
New England District