U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Erchonia Corporation 1/21/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3128

January 21,2011

Ref: 2011-DAL-WL-06

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Steven C. Shanks
President
Erchonia Corporation
2021 Commerce Drive
McKinney, Texas 75069

Dear Mr. Shanks:

During an inspection of your firm located in McKinney, TX, on November 17 through November 24, 2009, investigator(s) from the United States Food and Drug Administration (FDA) determined that your firm manufactures markets and distributes the Zerona MLS laser scanner for use in liposuction and body contouring. Under section 201 (h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321 (h), Zerona MLS laser scanner 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 are intended to affect the structure or function of the body.

1. Your Zerona Medical laser is adulterated under section 501 (f)(1)(B) of the Act, 21 U.S.C. § 351 (f)(1)(8), 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). Your Zerona Medical laser is also misbranded under section 502(0) 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 section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notificatio 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 C.F.R. § 807.81(a).

a. Our review of your firm's press releases posted on your website at http://www.erchonia.com/press-releases/[1] titled "Erchonia Presents New Laser Studies A2010 ASLMS Conference" revealed that they contain statements about clinical studies that represent or suggest that your Zerona laser devices are effective for new indications. A major change or modification in the intended use of the device requires a premarket notification submission, as required by 21 C.F.R. § 807.81 (a)(3)(ii). For example:

i. "Erchonia will be presenting a study it conducted using low level lasers to treat late stage Parkinson's disease.... Eight volunteers between 18 and 80 years with late stage PO participated in the non-controlled, non-randomized study and received low level laser treatments daily for two weeks.... All participants demonstrated a decrease in VAS for baseline to study endpoint."

ii. 'The second study Erchonia plans to present shows how low-level lasers may reduce low-density lipoprotein (LOL) .... Forty one patients between 18 and 65 years participated in the noncontrolled, non-randomized study. Participants received a 40 minute ZERONA laser treatment three times a week for two weeks... This study suggests that low level laser therapy may serve as a non-invasive way to reduce LOL in two weeks."

iii. "The third study explores how ZERONA laser impacts leptin levels, the hormone linked to hunger. Twenty volunteers between the ages of 18 and 65 participated in Erchonia's non-controlled, non-randomized study. ... All participants demonstrated a reduction in leptin levels compared to their baseline - on average, a 50% decrease. Since leptin levels are associated with hunger, the study shows how low level laser technology may noninvasively suppress the appetite."

b. Another press release titled, "Studies Shows Fat Reduction Laser Reduces Hunger and LOL Levels," dated May 5, 2009, contains the following statements:

i. "Erchonia Medical, the global leader in low level laser healthcare applications, announces today that its newest laser for body sculpting, Zerona, has been clinically shown to reduce the levels of the hunger-hormone, leptin, and lipoprotein (LOL). A 22 participant pilot study revealed that Zerona not only reduced circumferal inches ... but also lowered all patients' leptin levels and reduced low-density lipoprotein number in over 50% of the patients in just two weeks."

ii. "Suppressing the very hormones that may cause individuals to be overweight or obese can further aid Zerona patients with their weight-loss goals."