



NOV 19 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Ms. Leah Louis
Cellulite Reduction of New York
1045 Park Avenue
New York, New York 10028

Re: ES1 Therapeutic Massager

Dear Ms. Louis:

The Office of Compliance (OC) of the Food and Drug Administration (FDA) has reviewed your web site at the Internet address: <http://www.celluliteusa.com>. The site contains certain medical claims for the device commonly known as the ES1 therapeutic massager. This product is manufactured by LPG, USA, Incorporated, Fort Lauderdale, Florida.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act, the ES1 is considered to be a medical device because it is being used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers and/or distributors of medical devices obtain marketing clearance for their products from FDA before they are allowed to offer them for sale to the public. This serves to protect the public health by ensuring that new medical devices are safe and effective or substantially equivalent to other devices already legally marketed.

In April, 1998, FDA gave LPG permission to market the ES1 Therapeutic Massager for the following medical claims: relief of minor muscle aches and pains, temporarily increases local blood circulation, relaxes muscles locally, and *temporarily* reduces the appearance of cellulite (emphasis added). As a result, any distributor of the ES1 may also make these claims for the device.

However, when a manufacturer or distributor of the ES1 makes a significant change in the medical claims (intended use), such change(s) must first be cleared by FDA before implementation. On September 7, 1999, Mr. Byron Tart, Director, Promotion and Advertising Policy Staff (PAPS), discussed your web site and advised you that certain claims made for the ES1 were not acceptable because they had not been cleared by FDA prior to implementation.

A review of your current web site reveals that Cellulite Reduction of New York continues to make some of the same unlawful claims for which you were cited in our September 9 letter. Representative examples are as follows:

-“Reduce cellulite by following the Endermologie healthy lifestyle program;”

-“Most patients claim that it (Endermologie) reduces cellulite, contours the body, increases skin elasticity, facilitates lymphatic drainage;”

-“Renew the tone of your skin to soft and supple. Endermologie makes it possible with the ultimate advancement in body contouring and skin conditioning. A unique, whole body approach stimulates your body with deep, soothing motions that actually reduce the appearance of cellulite while defining your figure;”

-“...Collagen function is restored, toxins and abnormal water buildup is expelled, as the connective fibers are stretched. The result is a smoother, more contoured body;”

-“...Whole body approach to reducing cellulite. Reshape your body and improve skin tone with this painless procedure;”

-“...The body is reshaped, skin quality and texture are improved;”

-“...Removal of excess fluids and unhealthy metabolites;”

-“This translates into cutaneous resurfacing and tissue rejuvenation;”

-“...This technique (Endermologie) boosts the body’s major cleansing mechanisms, including lymphatic drainage, purging the inner environment contained within the body’s smooth and supple outer shell;”

-“...Many clients report being able to lose weight, especially fat weight, more easily while using the machine than they ever could before;”

-“In men, loose fat on the hips (love handles), chest (pectoral area) and the thighs can resemble cellulite.”

We also note that your web site contains a box titled “Links of Interest.” Clicking on this box takes the reader to several related sites discussing Endermologie and the ES1 device. Some of these sites contain testimonials from physicians and other consumers that also discuss unapproved uses of the ES1 device. Since these other web sites can easily be accessed by anyone in the United States, they may not contain any claims for the ES1 that have not been cleared by the agency. Representative examples of the sites and testimonial statements that we consider objectionable are as follows:

-<http://www.oprah.com>... This site contains claims that Endermologie may help get rid of cellulite by creating a skin fold that softens connective tissue and moves out tissue fluids. The ES1 may only be promoted for the temporary reduction in the appearance of cellulite. No data have been submitted to FDA showing that the ES1 softens skin folds or moves out tissue fluids.

-<http://www.channel2000.com>... This web site contains the phrase, “Cellulite treatment proven effective;” and, “It does an improvement to the skin tone and texture. Most patients, if they do it on a consistent basis, will, in fact, lose some inches.” Cellulite Reduction of New York must limit its cellulite claims to the temporary reduction in the appearance of cellulite. Also, may not claim that the ES1 improves skin tone or that it results in loss of inches. No claims for any type of weight reduction and/or body contouring are permitted.

-<http://www.abcnews.go>... Statement by Dr. Milan Jeckle indicating that Endermologie improves the elasticity, stimulates collagen, and helps the body flush more toxins and fatty waste. There is no evidence that the ES1 has the ability to improve elasticity, stimulate collagen, or flush toxins and/or fatty waste.

-<http://www.sonador.com>... This site contains the claim that cellulite can be removed permanently and that Endermologie can contour the body, improve skin tone, enhance figures, and eliminate the appearance of cellulite without surgery. None of these statements is true. The only acceptable language regarding cellulite reduction is the claim, “temporarily reduces the appearance of cellulite.” Another section of the site discusses Endermologie’s ability to “rid the body of toxins” and in “allowing weight reduction.” These claims are not permitted.

-<http://detnews.com>... This site mentions removing the appearance of cellulite without indicating that the process is temporary. It also mentions body contouring again which is not permitted.

-<http://www.kron.com>... This site quotes Ms. Kathleen Blazier as wanting to “get rid of the cellulite or fat bumps...” and claims that the device “may be used to soften scar tissue and reduce lymphedema, or swollen legs.” No data have been submitted to FDA demonstrating that the ES1 softens scar tissue or that it reduces lymphedema. Also, “getting rid of cellulite is not permitted.” When referring to cellulite reduction, you may only use the phrase. “temporarily reduces the appearance of cellulite.”

Claims that the ES1 can result in weight loss/reduction, loss of inches, body contouring, increases skin elasticity, results in lymphatic drainage or removal of toxins, renews skin tone, eliminates love handles, stretch marks, loose skin, scar tissue, reduces lymphedema, or reduces cellulite permanently, is a serious violation of FDA law. Because the ES1 is considered under the law to be held for sale each and every time that you use the device, you are considered to be a distributor of the ES1 and therefore, fall under FDA’s jurisdiction.

In legal terms, the ES1 is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. The ES1 is adulterated because you, as the distributor of the device, failed to obtain premarket approval based on information developed by you to show that your device is safe and effective for the claims that are represented on your web site. You have also misbranded the ES1 because you failed to submit information to FDA showing that your device is substantially equivalent to other similar devices that are legally in the marketplace.

The claim that Endermologie is the only FDA approved treatment for the temporary reduction in the appearance of cellulite is not accurate. The agency has granted this claim to at least three other manufacturers based on valid scientific evidence.

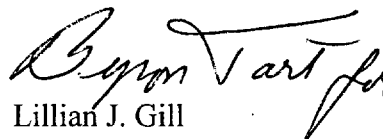
These violations of the law are not limited to the internet but would also apply to any labeling or promotional materials distributed by Cellulite Reduction of New York. You must review these other materials to assure compliance with FDA regulations.

You should take prompt action to correct these violations of the law. If you don't act immediately, FDA may take further action against you which may result in seizing your product inventory, obtaining a court injunction against further marketing of the ES1, or assessing civil money penalties against you.

You must take appropriate action to correct these violations now. Please submit a written letter to this office, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. You should include all steps you are taking to correct the problems identified above. If you need more time, let us know why and when we can expect a complete response. Please direct your response to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New York District Office. Please send a copy of your response to the District Director, Food and Drug Administration, New York District Office (HFR-NE100), 850 Third Avenue, Brooklyn, New York 11232-1593.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health