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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN - 5 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

Ms. Nathalie Guitay
President
LPG USA, Incorporated
3101 North Federal Highway
Suite 301
Fort Lauderdale, Florida 33306

Re: ES1 Endermologie and CM6G
Therapeutic Massager,
K954399

Dear Ms. Guitay:

The Food and Drug Administration (FDA) has reviewed a promotional journal distributed by LPG USA, Incorporated (LPG) titled, ENDERMOLOGIE which is directed to plastic surgeons and that discusses the use of the ES1 device. The ES1 is manufactured by LPG Systems, Valence, France, distributed by LPG, and is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

On June 4, 1997, [redacted] indicated to us that the ES1 device is identical to the CM6G device which LPG markets as a therapeutic massager. Our records indicate LPG distributes the CM6G as a therapeutic massager that was found to be exempt from the 510(k) premarket notification requirements on September 27, 1996 based on information that LPG provided to FDA's Office of Device Evaluation. As long as your claims are limited to those specified in the regulations under 21 CFR 890.5660 i.e., intended for medical purposes, such as to relieve minor muscle aches and pains, your device remains exempt.

However, LPG's brochure and other promotional materials reviewed by our office promote the ES1 as a "non-surgical alternative to liposuction," and as a device "which combines a rolling technique with variable and mobile suctioning." The device is described as one which is made up of two elements: a technical console and a treatment head "used to perform the aspirated hypodermal mobilization." Additionally, your brochure makes the following medical claims for the ES1:

- ..."acts on the hypodermal layer and can be used before, during, and after liposuction;"
- claims that the ES1 is indicated in post and pre-

operative cases, including cosmetic surgery, treatment of cellulite, the enhancement of liposuction "through aiding the absorption of hematomas, balancing the condition of the tissues of the lower limbs which sometimes react differently, pre-operatively softening the fibrous layer of the hypodermis to facilitate the passage of the canula and post-operatively treating persistent fibrosis;"

- claims that Endermologie using the ES1 unblocks circulation by increasing blood and oxygen flow in suffocated cellulite tissue and by accelerating the drainage of stagnant toxic wastes; helps to reduce the appearance of cellulite;

- claims that the ES1 reduces fibrosis, breaks down fats, "disorganizes fat clusters and helps adipocytes evacuate the fat storage,"

- stimulates tissues so that their natural elasticity is restored; claims that the device can increase skin tone and reduce dimpling;

- claims that the device can be used as an alternative to surgery and that it reduces recovery time.

Similar claims are also found on your joint web site with the Fountain of Youth Institute at the Internet home page address: http://afountainofyouth.com. The above listing is a representative example of medical claims made and is not meant to be all-inclusive. LPG, because of its promotional activities, has established the ES1 as a medical device subject to the 510(k) premarket notification filing requirements and removes the exemption.

Marketing the CM6G Therapeutic Massager as the ES1 device with the above claims causes these devices to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f), and do not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a), or approved applications for investigational device exemptions (IDE) under section 520(g).

The CM6G Therapeutic Massager as the ES1 device is also misbranded within the meaning of section 502(o) of the Act, in that notices or other information respecting the modification in the intended use(s) of the devices was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the devices were not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your CM6G Therapeutic Massager/ES1 device. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in

other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent 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 Florida District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Florida District Office (HFR-SE240), 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809.

Sincerely yours,

Byron Tart for

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