



Food and Drug Administration  
2098 Gaither Road  
Rockville, Maryland 20850

JUL 12 2000

**WARNING LETTER****VIA FEDERAL EXPRESS**

President and/or Chief Executive Officer  
Dermal Tone, Inc.  
6255 McLeod Drive Unit # 11  
Las Vegas, Nevada

Dear Sir:

We are writing to you because we have obtained information that has revealed a serious regulatory problem involving a product known as "Dermal Tone," which is marketed by your firm. The Dermal Tone is promoted and sold on the Internet at [www.dermaltone.com](http://www.dermaltone.com). See enclosed website material dated 6/29/00. This website material states that "The Dermal Tone is an electronic device which sends out tiny amounts of electricity to designated areas of your face which causes muscles to flex and relax, exercising them for you." The product is being sold Over the Counter (OTC) through mail order via the Internet and through an Infomercial.

With respect to the Dermal Tone, the website material represents, among other things, that it is a potential treatment for facial paralysis and Bell's Palsy; that facial muscles are then strengthened and toned as they lift and tighten your skin; that you can use exercise to reverse the signs of aging on your face; that lines from the nose to mouth, pouches at the corners of the mouth, and jawline definition have been improved; that prominence of fine lines and wrinkles around the eye area have almost vanished; that it enhances the circulation by stimulating the skin's blood supply; that this permits more oxygen and nutrients to aid in healthy cell regeneration which improves the skin texture and complexion; that it visibly firms and tightens facial contours back to their original position; that it will improve the elasticity of the skin; that eyelids are no longer puffy; that the attached stretched skin shrinks with a result of firmer, and more youthful looking skin; and that if you decide to have cosmetic surgery, you may continue the treatments afterward to maintain your results.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), the Dermal Tone is considered to be a medical device because it is intended to affect the structure or function of the body. See the above claims for the device. Also, because the Dermal Tone is intended to affect the structure or function of the body by providing electrical current to various facial muscles to repeatedly flex (contract) them, it is a device, even if no claims were made for its specific use. The Dermal Tone is similar in technology to a "powered muscle stimulator" device identified under 21 Code of Federal Regulations (CFR) 890.5850.

The law requires that manufacturers of medical devices obtain marketing clearance for their products from the Food and Drug Administration (FDA) before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that Dermal Tone, Inc., obtained marketing clearance before it began offering the Dermal Tone. The kind of information Dermal Tone, Inc., needs to submit in order to obtain this clearance is described in the enclosed material entitled "Premarket Notification 510(k) Regulatory Requirements for Medical Devices." In addition, since in terms of technology, the Dermal Tone device is similar to a "powered muscle stimulator," as referenced above, the enclosed "Guidance Document for Powered Muscle Stimulator 510(k)s" may be of assistance when submitting a marketing application to FDA. The FDA will evaluate this information and decide whether this product may be legally marketed.

Because Dermal Tone, Inc., does not have marketing clearance from FDA, marketing the Dermal Tone is a violation of the law. In legal terms, the product is adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. The product is adulterated under the Act because Dermal Tone, Inc., did not obtain premarket approval based on information developed by the firm that shows the device is safe and effective. The product is misbranded under the Act because Dermal Tone, Inc., did not submit information that shows its device is substantially equivalent to other devices that are legally marketed.

The law requires that device labeling bear adequate directions for lay use. However, because Dermal Tone is not safe except under the supervision of a practitioner licensed by state law to direct the use of the device, it is a prescription device for which adequate directions for lay use cannot be prepared or written. The law exempts a prescription device from adequate directions for lay use if it meets all of the conditions of 21 CFR 801.109 (copy enclosed).

The Dermal Tone does not meet all the conditions of 21 CFR 801.109. Specifically, the product is not sold only to or on the prescription or other order of the above referenced practitioner, for use in the course of his or her professional practice, as required by 21 CFR 801.109(a)(2). Rather, the Dermal Tone is sold over the counter through mail order, without the requirement for the referenced prescription or other order.

Because the Dermal Tone is a prescription device and does not meet all the conditions of 21 CFR 801.109, it is in violation of the law. In legal terms, the product is misbranded under Section 502(f)(1) of the Act.

The law also requires under Section 510 (j) of the Act that Dermal Tone be listed. See 21 CFR 807.20(a) (copy enclosed) for who is responsible for listing the Dermal Tone. Our records do not show that your firm or any other firm has complied with the above requirement. Because the Dermal Tone is not listed, it is in violation of the law. In legal terms, the product is misbranded under Section 502(o) of the Act.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties (see below). Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

With respect to civil money penalties, the FDA may assess these against you individually and Dermal Tone, Inc., for violations of Section 301(a) of the Act; i.e., the introduction or delivery for introduction into interstate commerce of any ... device... that is adulterated or misbranded. Under Section 303(f)(1)(A) of the Act, FDA may impose civil money penalties of up to \$15,000 on you as an individual, and a like amount on Dermal Tone, Inc., for each violation of a requirement of the Act relating to medical devices, up to a total of \$1,000,000 per respondent for all violations. In this case, a violation of referenced Section 301(a) occurs each and every time Dermal Tone, Inc., ships a device.

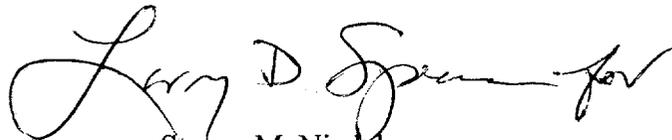
It is necessary for you to take action on these matters now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. Additionally, we ask that you provide the names and addresses of all domestic and foreign manufacturers and distributors from whom you obtain the Dermal Tone device. If you need more time, let us know why and when you expect

to complete your correction and to provide the above requested information. Please direct your response to William F. Defibaugh, Compliance Officer, Orthopedic, Physical Medicine, and Anesthesiology Devices Branch, Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, MD 20850.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issues of premarket clearance for your device, prescription device requirements, and listing requirements, and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at <http://www.fda.gov>.

A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the District Director, Food and Drug Administration, San Francisco District Office (HFR-PA100), 1431 Harbor Bay Parkway, Alameda, CA 94502-7070

Sincerely yours,

A handwritten signature in black ink, appearing to read "Steven M. Niedelman". The signature is fluid and cursive, with a large initial "S" and a long, sweeping underline.

Steven M. Niedelman  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health

Enclosures: As stated