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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

Warning Letter

VIA FEDERAL EXPRESS

Mr. Kenneth P. Callison
Director
Allied Health Association
8250 S. Akron Street, Suite 203
Englewood, Colorado 80112

Dear Mr. Callison:

We are writing to you because it has come to the attention of the Food and Drug Administration (FDA) that there may be a serious regulatory problem involving the product known as the Skinmaster microdermabrasion system, which is marketed by your firm.

Current information from your website at www.alliedhealth.net and a recent brochure entitled, "Turn Back the Hands of Time," revealed that the SkinMaster microdermabrasion system and other devices are being offered for commercial distribution. Furthermore, the list of seminars on your website indicates that you are demonstrating your devices and selling them to customers.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the human body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from 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 your firm or any other firm obtained marketing clearance before offering the SkinMaster microdermabrasion system for sale. Without marketing clearance from FDA, marketing the SkinMaster microdermabrasion system is a violation of the law. In legal terms, the device is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. The device is adulterated under the Act because neither you nor the manufacturer obtained premarket approval based on information developed by you or the manufacturer that shows the device is safe and effective. The device is misbranded under the Act because neither you nor the manufacturer submitted information that shows the device is substantially equivalent to other devices that are legally marketed.

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In addition to medical devices, FDA regulates manufacturers of radiation-emitting products. The SkinMaster microdermabrasion system is subject to these regulations. All laser products distributed in the United States (U.S.) must be certified as complying with the Federal laser product performance standard. These laser products must be reported to this office prior to distribution to end users, including doctors and medical facilities.

Please be advised that laser products manufactured after August 1, 1976, and marketed in the U.S. are subject to all applicable requirements of the Federal performance standard for laser products. It is unlawful for laser products to be introduced into U.S. commerce if they are not certified and/or if they fail to comply with the standard. The performance standard (21 CFR 1040.10 and 11), reporting guides, and related regulatory information are available from our website at:
<http://www.fda.gov/cdrh/radhlth>.

This letter is not intended to be an all-inclusive list of deficiencies associated with the marketing of your medical devices. It is your responsibility to ensure adherence to each requirement of the Act and federal regulations. The specific violations noted in this letter may apply to other devices marketed by your firm. You are responsible for the promotion, labeling, and marketing of the devices you place in commercial distribution to assure compliance with applicable regulations.

You should know that this serious violation 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, injunction, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, state the reason for the delay and the time within which the corrections will be completed.

Your website also promotes hyperbaric chambers, laser hair removal devices, the Tri-Phasic Resonators, and the Bio-electric facelift device. Are these being sold as prescription devices? Please identify the manufacturers and model(s) you are marketing so that we may verify their marketing status.

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We are concerned that you are promoting and offering hyperbaric chambers for sale for conditions such as aches and pains, bruises, sprains, illness and injury, stress, asthma, memory loss, strokes, aging, weight loss, and brain injuries. This device has not received clearance for any of these indications.

The device depicted on your website appears to be a chamber that is manufactured by [REDACTED] under the name "[REDACTED]" or "[REDACTED]". This chamber was only cleared for marketing for acute mountain sickness and the mild symptoms associated with it. Neither it nor any other manufacturer's chamber has marketing clearance for the indications for use listed above. If your devices do not have the required marketing clearance for all of these indications for use then they are in violation of the law.

With regard to the Tri-Phasic Resonator promoted on your website and in brochures, we understand that you have sent copies of your labeling to Mr. Steven Budabin, Promotion and Advertising Policy Staff, Office of Compliance. Please clarify whether any units have been sold to date.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by reviewing our website at <http://www.fda.gov/cdrh> or by contacting the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at (800) 638-2041.

Please submit your response to this letter to: Mr. George Kroehling, Chief, General Surgery Devices Branch, Division of Enforcement I (HFZ-323), 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 Denver District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Denver District Office (HFR-SW200), 6th & Kipling Street, Denver, CO. 80225-0087.

If you have any questions, feel free to contact Ms. Cory Tylka of the General Surgery Devices Branch at (301) 594-4595, ext. 170 or FAX: (301) 594-4636.

Sincerely yours,



Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health