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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC 14 2001

Warning Letter

VIA FEDERAL EXPRESS

Mr. Giovanni Grattataso
President
Biorem s.r.l.
Via Angrisani 18/A
84043 Agropoli (SA)
Italy

Dear Mr. Grattataso:

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 manufactured and marketed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a medical device because it is 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 obtained marketing clearance before offering the product for sale. The kind of information you need to submit in order to obtain this clearance is described on FDA's medical device website under premarket notification at: www.fda.gov/cdrh/devadvice. FDA will evaluate your submitted information and decide whether your device may be legally marketed.

Because you do not have marketing clearance from FDA, marketing this device 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. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows the device is substantially equivalent to other devices that are legally marketed.

In addition to medical devices, FDA regulates manufacturers of radiation-emitting products. Due to the laser accessory, the SkinMaster microdermabrasion device 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 medical facilities (see 21 CFR 1000-1040.11).

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 manufacturers: (1) to introduce such products into U.S. commerce if they fail to comply with the standard, or (2) to fail to submit laser product reports.

The manufacturer is required to report the product by submitting a Laser Product Report to this office (see 21 CFR 1002.10). In addition, 21 CFR 1002.11 requires submission of Annual Reports by September 1 of each year. The performance standard (21 CFR 1000-1040.11), 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 laser dermabrasion 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 represent practices used in other product 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 know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. Given the serious nature of these violations of the Act, all devices manufactured by Biorem s.r.l., Agropoli, Italy, may be detained upon entry into the U.S. without physical examination until these violations are corrected. 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.

It is necessary for you to take action on this matter now. Please let this office know what steps you are taking to correct the problem within 15 working days from the date you received this letter. We also ask that you explain how you plan to prevent this from happening again.

If you need more time, let us know why and when you expect to complete your correction. Additionally, please advise us of any action you have taken or plan to take to address the previously distributed products.

Please submit your response to: Director, Division of Enforcement I (HFZ-323), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland, 20850, USA.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter only pertains to the issues of premarket clearance and radiological health 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 reviewing our website at http://www.fda.gov/cdrh or by contacting the Division of International and Consumer Small Manufacturers Assistance (DICSMA) at (800) 638-2041 or (301) 443-6597.

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

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