



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M2261N

DEC 14 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Warning Letter

VIA FEDERAL EXPRESS
RETURN RECEIPT REQUESTED

Mr. Adriano Tessiore
General Manager
Boston Electtrodomeistici S.r.l.
Corso Matteotti, 26
16035 Rapallo
Italy

Dear Mr. Tessiore:

We are writing to you because it has come to our attention that your firm, Boston Electtrodomeistici S.r.l. has been shipping the Boston Hair Laser to American customers without receiving marketing clearance from the Food and Drug Administration (FDA).

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. Claims of promoting hair regrowth, increasing the number of red corpuscles and blood flow, treating hair loss and scalp problems, repairing damaged hair, and other hair or scalp therapy are medical claims rather than cosmetic, and would require FDA clearance for distribution in the United States.

Because your firm does 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.

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Additionally, I wish to bring to your attention that promotional literature being distributed by Salon Interiors has been carrying all of the above unapproved medical claims as well as the false statement that the device is FDA approved based, perhaps, on a misunderstanding that compliance with the Federal laser product performance standard constitutes approval.

The laser product report and supplements submitted in 1989 and 1990 demonstrated that the Tricholic laser hair treatment system complied with the Federal laser product performance standard, the regulations covering radiation safety. Let me remind you that the manufacturer, not the FDA, certifies that its laser product complies with the Federal laser product performance standard; there is no FDA approval of radiation safety. The premarket approval (PMA) process where the manufacturer must demonstrate safety and effectiveness in the medical indication for use in order to receive marketing clearance is totally independent from the laser product regulations. To date, your firm has only submitted a laser product report on the Tricholic laser with no indication of the relationship between it and the Boston Hair Laser, and has no premarket approval.

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, imports detention, or assessing civil money penalties. 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 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. Additionally, please advise us of any action you have taken or plan to take to address the previously distributed product.

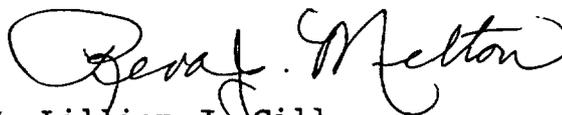
Please submit your response, clearly referencing Accession Number 8910516, to: Director, Division of Enforcement I (HFZ-323), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland, 20850, USA. Send a copy of your response to the FDA New Jersey district office at: FDA (HFR-MA340), Waterview Corporate Center, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054, USA.

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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 contacting our Division of Small Manufacturers' Assistance at phone number: 1-800-638-2041, FAX: 301-443-8818, or through our Internet website at <http://www.fda.gov>.

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,



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

CC: Mr. Walter Siegordner
President
The Aurora Group/Salon Interiors
62 Leuning Street
So. Hackensack, NJ 07606

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