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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 7 2008

Warning Letter

Via Federal Express

Dr. Charles Maricle
President
Sunetics International Corporation
4760 S. Pecos Rd., Suite 103
Las Vegas, Nevada 89121-5828

RE: Sunetics Laser Hair Brush
Sunetics Laser Skin Brush (aka Laser Skin Therapy System)

Dear Dr. Maricle:

The Food and Drug Administration (FDA) has learned that your firm is marketing the Sunetics Laser Hair Brush and the Laser Skin Brush in the United States (U.S.) without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Under section 201(h) of the Act, the Sunetics Laser Hair Brush and the Sunetics Laser Skin Brush are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body. Specifically, your web site, According to your web site, www.sunetics.com, the Sunetics Laser Hair Brush and the Sunetics Laser Skin Brush are laser devices that are intended to grow hair and to treat various skin conditions such as acne, skin pigmentation, burns, wounds and pain relief.

A review of our records reveal that you have not obtained marketing approval or clearance began you began offering your products for sale, which is a violation of the law. Specifically, the devices are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), in that it is a class III device under section 513(f), 21 U.S.C. 360C9F), and you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IED) under section 520(g) of the Act, 21 U.S.C. 360j(g). The devices are also misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by sections 510(k) of the Act, 21 U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency. 21 CFR 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at http://fda.gov/cdrh/devadvice/3122.html. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

We acknowledge that your firm submitted a premarket notification for the Laser Hair Brush on January 22, 2008, which is currently under review. It is a violation of the law to commercially distribute the device until FDA issues an order permitting it to be marketed. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and /or civil money penalties. Also, Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please let this office know in writing what steps you have taken to correct the problem within fifteen (15) working days from the date you receive 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. Please direct your response to Thomas C. Knott at the Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, and facsimile at 240-276-0114. We remind you that only written communications are considered official.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of devices. This letter pertains only to the issue of premarket review for your device and does not necessarily address other obligations you have under the law.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

Cc:

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Charles Maricle
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