



DEPARTMENT OF HEALTH & HUMAN SERVICES

93940d  
Public Health Service  
Food and Drug Administration

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**W/L 29-03**

April 8, 2003

Mr. Maxie L. Tay  
President and CEO  
OSIM (USA), Inc.  
1980 W. Corporate Way  
Anaheim, California 92801

Dear Mr. Tay:

An inspection conducted at your facility on December 13, 16-18, and 23, 2003, by the Food and Drug Administration (FDA) revealed a serious regulatory problem involving products known as OS-898 Pro-Reflexologist, OS-899 eReflexologist, OS-205 Pro-Therapist Electrical Stimulator, OS-505 Automatic Blood Pressure Monitor, OS-506 Computerized Blood Pressure Monitor, OS-508 Wrist Blood Pressure Monitor, and OS-509 Computerized Blood Pressure Monitor. Under a United States Federal Law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices because they are intended for use in the diagnosis or treatment of a medical condition or intended to affect the structure or function of the body. 21 U.S.C. § 321(h).

The law requires that manufacturers and distributors of medical devices obtain marketing clearance or approval 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.

A review of our records has determined that there is no marketing clearance or approval in effect for the above-referenced devices that you are offering for sale in this country. Each of these devices requires a premarket notification submission under section 510(k) of the Act (21 U.S.C. § 360(k)) and clearance from FDA before they may be legally introduced into United States commerce. The kind of information you need to submit in order to obtain this clearance is described in FDA regulations at 21 Code of Federal Regulations, Part 807. You may also find the requirements at <http://www.fda.gov/cdrh/devadvice/3122.html>. After you submit this information, FDA will evaluate it and decide whether your devices may be legally marketed in this country.

You have two devices that appear to be therapeutic massagers – the OS-898 Pro-Reflexologist and OS-899 eReflexologist. Although “therapeutic massagers” are classified in 21 CFR 890.5660 and are exempt from the premarket notification requirements, the uses for which you are promoting these devices – to rid the body of impurities, tone muscles, reduce fatigue, promote healing, prevent muscle degeneration and arthritis in joints, and reduce swelling and inflammation – go beyond the limitations of the exemption because they are different from the intended use of a legally marketed device in that generic type of device. See 21 CFR 890.9. Accordingly, you must submit premarket notification submissions under section 510(k) of the Act and obtain clearance from FDA before you may legally introduce these products into United States commerce.

Because none of the above-referenced devices have marketing clearance or approval from FDA, they are in violation of the law. In legal terms, the devices are misbranded under section 502(o) of the Act, for failure to notify the agency of your intent to introduce the devices into commercial distribution, as required by section 510(k) of the Act. Until you have submitted these notifications and received orders in response from FDA notifying you that your devices have been found to be substantially equivalent to legally marketed devices, and thus are cleared for marketing, your devices are also adulterated under section 501(f)(1)(B) of the Act, for failure to obtain FDA premarket approval. (For products that require the submission and approval of a premarket approval application (PMA), the notification required by section 510(k) of the Act is deemed to be satisfied when a PMA is pending before the agency, 21 CFR 807.81(b), but marketing may not begin until premarket approval is granted.)

You should know that this is a serious violation of the law and 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 products, 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.

Given the serious nature of these violations of the Act, these devices may be detained without physical examination upon entry into the United States until these violations are corrected.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the noted violations. We also ask that you explain how you plan to prevent this from happening again. If you need more time to respond, let us know why and when you expect to complete your correction.

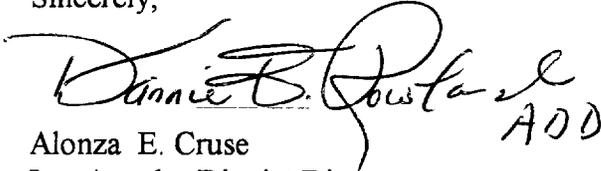
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Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the failure of your devices to have premarket clearance and does not necessarily address 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, International and Consumer Assistance (DSMICA) at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Senior Compliance Officer Dannie E. Rowland at 949-798-7649. Your reply should be addressed to:

Acting Director of Compliance  
U.S. Food and Drug Administration  
19900 MacArthur Blvd.  
Irvine, CA 92612

Sincerely,



*Dannie E. Rowland*  
ADD

Alonza E. Cruse  
Los Angeles District Director

cc: State Department of Public Health  
Environmental Health Service  
ATTN: Chief Food and Drug Branch  
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