



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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6/10/98

JUN 8 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Warning Letter

VIA FEDERAL EXPRESS

Mr. Gareth R. Ross-Crossley
Chief Executive Officer (Managing Director)
Pain Clinics Australia Pty Ltd.
Suite 1/13 Chester Street
Oakleigh, Victoria 3166
Australia

Dear Mr. Ross-Crossley:

We are writing to you because it has come to our attention that your firm, Pain Clinics Australia Pty Ltd. has been shipping the Ozlaze 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. Premarket application information is being sent to you under separate cover from the Center for Devices and Radiological Health (CDRH) Division of Small Manufacturers' Assistance (DSMA).

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.

Additionally, I wish to bring to your attention that promotional literature being distributed by B.B.R.H. has been carrying various objectionable phrases that claim or imply FDA approval of

your device. Identification of the Accession Number assigned to your laser product report ("US FDA Certification #9810027") can easily be misconstrued as a clearance, as is "a unique US FDA-Approved Class 1 Laser Certification. This assures their safety for use by anyone." This phrase is also found on an Ozlaze specification sheet that appears to be included with information from the Australian Radiation Laboratory.

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 submitted an incomplete laser product report and has no premarket approval.

With regard to your laser product report and supplement, Accession number 9810027-00 & 01, dated 12/29/97 and 4/8/98, we have the following comments and requests.

1. Please clarify the relationships between both the firm names Emmetglen and Pain Clinics, as well as the laser product's designations: Infralaze, Infralaze Excel, Auslaze, and Ozlaze. All these terms have appeared in the initial and supplemental reports, causing confusion.
2. Please submit a copy of your manufacturer's certification and identification label, as required by 21 CFR 1010.
3. Please submit quality assurance procedures in response to part 8 of the report, to demonstrate compliance with the performance standard during manufacturing. 21 CFR 1010.2 requires that certification be based on a testing program in accordance with good manufacturing practices. Lack of an adequate testing program is a prohibited act under section 538 of the Federal Food, Drug, and Cosmetic Act.
4. Please submit a copy of the product's operation and service manuals in response to part 4.1 of the report, to show compliance with 21 CFR 1040.10(h).
5. Please submit copies of all current promotional literature on your certified laser products in response to part 4.2.

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 9810027, 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 Ms. Serrah Namini, Electro Optics Specialist, FDA (HFR-PA2545), 19900 MacArthur Blvd., Suite 300, Irvine, CA 92714, 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 contacting DSMA 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. Ben Runnels
Chief Executive Officer/President
B.B.R.H. International
2082 South Grand Avenue
Santa Ana, CA 92705