



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 11 2000

WARNING LETTER

VIA FEDERAL EXPRESS

Ref:OC:I1-1840

Mr. Mohd Hamdi
Fradama S.A.
Rue de Vermont, 9A
1202 Geneva
Switzerland

Dear Mr. Hamdi:

During an inspection of Dr. Alvin Stjernholm's facility located in Lakewood, Colorado, on April 20, 1999, our investigators determined that the doctor has purchased approximately [REDACTED] Fradama Soft Laser 632 laser systems in his facility and he stated that he had sold [REDACTED] Fradama dental units. A field examination was performed on one unit and numerous noncompliances with the Federal laser product performance standard were revealed. It was determined that your firm has been manufacturing laser therapy devices and distributing them in the United States (U.S.). Laser therapy devices are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that the Fradama laser devices are adulterated under section 501(f)(1)(B) of the Act, in that they are class III devices under section 513(f) and do not have approved applications for premarket approval in effect pursuant to section 515(a) or approved applications for an investigational device exemption under 520(g).

Furthermore, the inspection revealed that the Fradama laser devices are misbranded under section 502(o) of the Act, in that your establishment has not been registered and that the devices were not included in a list required by section 510(j) and notices or other information respecting the devices were not provided to the Food and Drug Administration (FDA) as required by section 510(k).

Be advised that, in addition to the above, laser products manufactured after August 1, 1976, and imported into the U.S. are subject to all the applicable requirements of the Federal performance standard for laser products, 21 CFR 1040.10 and 1040.11. 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 reports as required by 21 CFR 1002. The Federal performance standard for laser products applies to all laser products, whether for human or animal use. This means the Soft Laser therapy lasers sold by you to Americans for either human or animal treatment are noncompliant with the performance standard.

According to our records, information regarding Federal laser regulations was sent to you on March 22, 1993, and referenced in your response to this office dated April 14, 1993.

Listed below are noncompliances with the Federal laser product performance standard encountered during the inspection.

1. 21 CFR 1010.2. The Soft Laser 632 lacks a certification label stating that the product complies with the Federal laser product performance standard. The certification represents a testing program that is in accordance with good manufacturing practices.
2. 21 CFR 1010.3. The Soft Laser 632 lacks an identification label giving the full address of the manufacturing location and date of manufacture.
3. 21 CFR 1040.10(f)(2)(iii). The Soft Laser 632 lacks fail-safe or redundant safety interlocks for portions of protective housing which are designed to be removed during operation or maintenance and, when opened, could permit unnecessary access to laser radiation levels greater than Class I. This would include the fiberoptic connector port.
4. 21 CFR 1040.10(f)(3). The Soft Laser 632 lacks a remote interlock connector, required for all Class IIIb and IV laser products.

5. 21 CFR 1040.10(g)(2) and (4). The Soft Laser 632 lacks the required Warning logotype label. Please note that 21 CFR 1040.10(g)(8)(i) requires the phrase "Visible and Invisible" prior to "Laser Radiation."
6. 21 CFR 1040.10(g)(6). The Soft Laser 632 lacks noninterlocked protective housing labels on any portions of protective housing that are not interlocked and, if opened, could permit unnecessary access to laser radiation levels above Class I. Please note that 21 CFR 1040.10(g)(8)(i) requires the phrase "Visible and Invisible" prior to "Laser Radiation."
7. 21 CFR 1040.10(h)(1)(iii). The Soft Laser 632 Operating instruction manual lacks locations of the labels required by 21 CFR 1040.10(g) and 1040.11(a)(3).
8. 21 CFR 1040.10(h)(1)(iv). The Soft Laser 632 Operating instruction manual lacks the "Caution - use of controls or adjustments..." warning statement.
9. 21 CFR 1040.11(a)(1). The Soft Laser 632 units sold for human use lack a means for measurement of the radiation levels intended for irradiation of the human body.
10. 21 CFR 1040.11(a)(2). The Soft Laser 632 Operator's manual lacks calibration procedures and schedule, required to be supplied with each Class III and IV medical laser product. Although we would not object to your inclusion of statements such as you have to the effect that only authorized representatives of Fradama may perform the procedure and that user recalibration would invalidate the warranty, the requirement is clear that the instructions must be supplied to the purchaser. You will note that the IEC 825 standard has a similar requirement.
11. 21 CFR 1040.11(a)(3). The Soft Laser 632 lacks an aperture label as specified by this section.

Please note that for the labeling noncompliances the labels on the products, the labeling sections in the operator and service manuals, label reproductions on sales literature, and labeling procedures followed in manufacturing must be revised.

Section 538(a) of the Act, Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or from failure to submit required reports. Failure to respond to this letter may be considered to be in violation of section 538(a)(4) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA) applicable to distribution and recordkeeping activities.

You should take prompt action to correct these deficiencies. Failure to promptly correct these deficiencies may result in regulatory action being initiated by the FDA without further notice. These actions may include, but are not limited to, seizure, imports detention, and/or imposition of civil penalties. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

Due to the seriousness of the violations, these devices are subject to automatic detention without physical examination under Import Alert 95-03.

You must respond in writing within 15 working days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been shipped to the U.S. or to your Canadian distributor, Jayvan Enterprises, in anticipation of shipment to the U.S., and specify whether they were certified.

1. Refutation - You may submit your views and evidence to establish that the alleged noncompliances do not exist.
2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

3. Purchaser Notification and Corrective Action - If you neither refute the noncompliances nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.
 - a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.
 - b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

The following noncompliances with the regulations regarding reports and recordkeeping were observed:

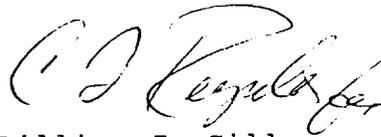
1. 21 CFR 1002.10. Laser product reports have not been received on the Soft Laser 632 system.
2. 21 CFR 1002.13. Annual reports have not been received on the Soft Laser 632 family of lasers.

Your response should be sent to: General Surgery Devices Branch, Division of Enforcement I (HFZ-323), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850 USA.

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Please send a copy of your response to: Compliance Branch (HFR-SW240), Food and Drug Administration, Denver District Office, P.O. Box 25087, 6th and Kipling St., Denver, CO 80225-0087 USA. If you have further questions on these requirements, please contact Ms. Cory Tylka of the General Surgery Devices Branch at phone: (301) 594-4595 ext. 170, or FAX: (301) 594-4636.

Sincerely yours,



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

CC: Dr. Jack Cornet
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