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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M3145M

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

VIA FEDERAL EXPRESS

NOV 12 1999

WARNING LETTER

Ref: OC:11-1837

Dr. Alvin Stjernholm  
5800 West Alameda Avenue  
Lakewood, Colorado 80226

And

Mr. William J. Stroupe  
President  
Bio-Laser Response Corp.  
7238 Timbercrest Lane  
Castle Rock, Colorado 80104

Dear Dr. Stjernholm and Mr. Stroupe:

During an inspection of Dr. Stjernholm's office in Lakewood, Colorado, on April 20, 1999, and Bio-Laser Response Corp. located in Castle Rock, Colorado, on April 21-22, 1999, our investigators determined that Bio-Laser Response Corp. manufactures laser therapy devices. Furthermore, in a letter dated February 4, 1999, from Dr. Stjernholm to Mr. Stroupe, Dr. Stjernholm describes himself as the Bio-Laser specification developer. As specification developer and manufacturer you both are manufacturers as defined in Title 21, Code of Federal Regulations (CFR), 820.3(o) and 806.2(g). 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 your laser therapy 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 investigational device exemptions under 520(g).

The laser therapy devices are also adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in 21 CFR Part 820.

Page 2 - Dr. Stjernholm and Mr. Stroupe

Furthermore, the inspection revealed that your laser therapy devices are misbranded under section 502(o) of the Act, in that your establishment was not registered under section 510, and that the devices were not included in lists 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).

Please be advised that, in addition to the above, laser products manufactured after August 1, 1976, are subject to all the applicable requirements of the Federal performance standard for laser products, 21 CFR 1040.10 and 1040.11. For the purposes of these regulations, manufacturer is defined as a person engaged in the business of manufacturing, assembling, or importing. It is unlawful for manufacturers: (1) to introduce such products into 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.

We understand that, based on discussions during the inspections, you both are now fully aware of the FDA's regulatory authority and the specific requirements with which you must comply, in order to market a product subject to both the medical device and electronic product radiation control sections of the Federal Food, Drug and Cosmetic Act. Mr. Stroupe has stated that he will no longer market the Bio-Laser product for human use; nevertheless, the product must comply with the Federal performance standard for laser products. In addition, all the devices shipped prior to any corrections remain adulterated and misbranded medical devices and noncompliant laser products, requiring corrective action.

Listed below are noncompliances with the Federal laser product performance standard encountered during the above-referenced inspections and subsequent review of the reports on the Bio-Laser 1000 and 2000, dated July 20, 1999, Accession Numbers 9911198-00 and -01.

1. 21 CFR 1040.10(f)(3). The Bio-Laser 1000 and 2000 lack a remote interlock connector, required for all Class IIIb and IV laser systems.

2. 21 CFR 1040.10(f)(5)(i). The Bio-Laser 1000 and 2000 audible emission indicator does not sound continuously so as to indicate laser emission during treatment. During the second or second "off" period access to radiation levels exceed Class I and the allowable ocular maximum permissible exposure level established in the American National Standards Institute (ANSI) Z136.1 standard.
3. 21 CFR 1040.10(f)(6). The Bio-Laser 2000 beam attenuator, in taking seconds to attenuate the beam, does not prevent access to radiation levels greater than Class I and the allowable ocular maximum permissible exposure level established in the ANSI Z136.1 standard.
4. 21 CFR 1040.10(g)(6). The Bio-Laser 1000 and 2000 lack noninterlocked protective housing labels on the handpiece.
5. 21 CFR 1040.10(h)(1)(iii). The Bio-Laser 1000 and 2000 Operating instructions lack reproductions of the aperture label and noninterlocked protective housing labels.
6. 21 CFR 1040.10(h)(1)(iv). The Bio-Laser 1000 and 2000 Operating instructions lack the "Caution - use of controls or adjustments..." warning statement.
7. 21 CFR 1040.11(a)(1). The Bio-Laser 1000 and 2000 units sold for human use lacked a means for measurement of the radiation levels intended for irradiation of the human body.

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. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firms' manufacturing and quality assurance programs. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systemic problems you must promptly initiate permanent corrective actions. 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.

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, injunction, and/or imposition of civil penalties.

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 produced and the number of such products that have left the place of manufacture and specify whether they were certified. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

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 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 noncompliance with the regulations regarding reports and recordkeeping was observed:

21 CFR 1002.13. Annual Reports from Bio-Laser Response Corporation have not been received.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may introduce such products into commerce for veterinary use.

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.

Page 6 - Dr. Stjernholm and Mr. Stroupe

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

Sincerely yours,

*Lillian J. Gill*

*for*

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

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