



(Purged)

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

Ref:OC:I1- 1896

via FEDERAL EXPRESS

Alex A. Yahal
General Manager
Yahal USA
706 South Hill Street, Suite 900
Los Angeles, California 90014

Dear Mr. Yahal:

This letter is written to advise you of items of noncompliance with the Federal Laser Performance Standard encountered during an inspection conducted by Suzie Kent, Pacific Region Electro-Optics Specialist, of Yahal USA on January 4, 2001 in Los Angeles, California. Items of noncompliance are also cited from review of product report 0110224 for Yahal USA's universal laser welding equipment, Model LDW4.

1. 21 CFR 1010.2 states that all electronic product manufacturers, including manufacturers of laser products, are required to affix certification labels on their products. Certification labels indicate that laser products comply with the Federal Laser Performance Standard and are based on the manufacturers quality control and testing. It was observed during the inspection that no certification labels were affixed to your products. The label contained in report 0110224 is inadequate and must identify the specific section of the Code of Federal Regulations (i.e. 21 CFR 1040.10 or 21 CFR Chapter 1, Subchapter J).
2. 21 CFR 1010.3 states that all electronic product manufacturers, including manufacturers of laser products, are required to affix identification labels on their products. Identification labels provide contact information for the manufacturer and indicate the month and year of manufacture of the products. It was observed during the inspection that no identification labels were affixed to your products. The label contained in report 0110224 is inadequate and must also identify the month and year of manufacture.
3. 21 CFR 1040.10(f)(2) states that Class IV laser products must have redundant or fail-safe interlocks for portions of the protective housing that may be removed during operation when such removal could permit unnecessary access to Class IV radiation. Fail-safe interlocks must prevent removal of the interlocked protective housing during failure or fail in such a way to prevent access to the laser radiation. The description of optional front and bottom access panels in report 0110224 indicates that these panels are used to insert larger pieces of material for welding and do not remain open during welding. As such, these panels must incorporate adequate safety interlocks to prevent exposure to unnecessary Class IV laser radiation. The

interlocks described in report 0110224 for the optional front and bottom access panels of the product are inadequate because they are not redundant or fail-safe.

4. 21 CFR 1040.10(f)(3) states that Class IV laser products must incorporate a remote interlock connector. The remote interlock connector must have an electrical potential difference equal to or less than $130 V_{rms}$ and prevent access to Class IV laser radiation when the terminals of the connector are open. No remote interlock connector is described in report 0110224.
5. 21 CFR 1040.10(f)(10) states that Class IV laser products must incorporate a manual reset mechanism. The manual reset mechanism must be available to enable resumption of laser emission when the remote interlock is used or if power is interrupted for a duration to equal to or greater than 5 seconds. No manual reset mechanism is described in report 0110224.
6. 21 CFR 1040.10(g)(3) states that Class IV laser products must have labels bearing the appropriate classification designation and warning logotype as specified in the standard. It was observed during the inspection that no Class IV warning logotypes were affixed to the products. The product classification and warning logotype labels contained in report 0110224 adequately address this noncompliance.
7. 21 CFR 1040.10(g)(5) states that all laser products must have aperture labels indicating each aperture through which laser radiation is emitted. This label must read "AVOID EXPOSURE - Invisible laser radiation is emitted from this aperture." It was observed during the inspection that no aperture labels were affixed to the products. The aperture label contained in report 0110224 adequately addresses this noncompliance.
8. 21 CFR 1040.10(g)(6) states that all laser products must have non-interlocked protective housing labels for each portion of the protective housing which has no safety interlock and may be removed during operation. This label must read "DANGER - Invisible laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." It was observed during the inspection that no non-interlocked protective housing labels were affixed to the products. The front and bottom panels must be interlocked to prevent unnecessary access to the Class IV laser radiation. This observation will no longer be applicable once safety interlocks are provided on the front and bottom panels of the product.
9. 21 CFR 1040.10(h)(1)(i) states that user information must contain adequate instructions for operation, including warnings and precautions to avoid possible exposure to Class IV laser radiation. This information is in part provided in form of beam path diagrams indicating protective housing, beam attenuators, viewports, and targets. Report 0110224 and the user information do not contain an adequate description of the external and internal laser radiation fields and paths.

10. 21 CFR 1040.10(h)(1)(iii) states that user information must contain legible reproductions of all labels affixed to the products and indicate their positions on the products. It was observed during the inspection that user information did not contain reproductions of the labels affixed to the products. The user information submitted with report 0110224 adequately addresses this noncompliance.
11. 21 CFR 1040.10(h)(1)(iv) states that user information must contain a listing of all controls, adjustment and procedures for operation and maintenance. A warning statement must also be included that reads "Caution - use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure." It was observed during the inspection that user information did not contain this required information.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (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 to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum penalty of \$300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 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. 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 failures to comply 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 noncompliance 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 failures to comply with the regulations regarding reports and record keeping were observed:

1. 21 CFR 1002.10 states that laser product manufacturers are required to submit product reports to FDA/CDRH. Product reports describe electronic products and how they comply with the appropriate performance standard. During the inspection it was observed that product reports were not available for review. Report 0110224 adequately addresses this requirement, although there are several items indicated in this letter that must be corrected in the report.
2. 21 CFR 1002.13 states that all electronic product manufacturers, including manufacturers of laser products, are required to submit annual reports to FDA/CDRH. Annual reports summarize production and recordkeeping activities conducted by electronic product manufacturers. During the inspection it was observed that annual reports were not available for review.

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 resume introduction of these products into commerce.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a **copy** of your response to: Director, Compliance Branch, Los Angeles District Office, Food and Drug Administration, 19900 Mac Arthur Blvd, Suite 300, Irvine, California 92612-2445. If you have further questions on these requirements, please contact LT Sean Boyd of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

Christy Foreman for

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

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cc: SMBoyd
EPB Board
EPB Files
Kent (HFR- PA2545)
LOS-DO (HFR- PA200)
LOS-DO Compliance Branch (HFR- PA240)
RRHR- PA (HFR- PA19)
DE3 Chron File
OC Chron File
OC Read File
HFZ-325
HFA-224
HFC-135
HFC-210
HFC-240 (COMSTAT)
HFZ-305 (purged)
HFI-35 (purged)