



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

HFI-35
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FEB 24 1999

WARNING LETTER

Ref:OC:I1-1816

via Federal Express

Mr. Bear Hsiung, General Manager
Limate Corporation
3F, No. 15, Lane 28
Huan-San Road, Sec 1
Nei-Hu
Taipei, Taiwan
R.O.C.

Dear Mr. Hsiung:

This letter is written to advise you of items of noncompliance with the Federal performance standard for laser products, 21 CFR 1040.10 and 1040.11, of a laser kit, Model DIY, identified as being produced by Limate Corporation. The following items of noncompliance were encountered during evaluation of a sample of this product collected from a shipment identified as Entry No. F83-0164905-6 consigned to Lasermate Corporation, 1977 W. Holt Avenue, Pomona, CA 91768.

1. 21 CFR 1010.2 and 1010.3: Certification and identification. There were no instructions for certification or for providing the required identification information. Please refer to our laser notice number 13, copy enclosed, that addresses these requirements as they apply to laser products that are provided in kit form.
2. 21 CFR 1040.10(c): Classification. The product was incorrectly classified as a Class II laser product having an output of less than 1mW. However, paragraph B.4 of the user instructions indicates that the product incorporates a control by which the output power of the pointer may be adjusted to an output of more than 1mW. Laser products having an output power of more than 1mW but not more than 5mW in the visible range would be Class IIIa. We also note that the Model DIY is listed on your Internet site as a Class IIIa laser product.
3. 21 CFR 1040.1040.10(g)(2)(ii): Labeling requirements. The kit included an incorrect Class II warning logotype label for this Class IIIa laser product.
4. 21 CFR 1040.10(h)(1)(i): User instructions. The user instruction failed to include directions for the purchaser/assembler of the kit to affix the warning logotype label to the product. Laser products provided in kit form must include complete instructions that will assure full compliance with the standard when the product is assembled in accordance with the instructions provided with the kit.

We understand this shipment has been denied entry into the United States (U.S.). Therefore, we will not request submission of a corrective action plan (CAP) for this particular shipment.

However, for any similar noncompliant laser product that may have been imported into the U.S., you are hereby advised that Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act) requires the submission of notifications as specified at 21 CFR 1003 and 1004. The Act also prohibits any manufacturer from certifying or introducing into commerce or importing of laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain records or to submit required reports.

You must respond within 15 days of the date of receipt of this letter to each of the items listed above. Your response must describe what actions you will take or what changes you will make to your products to bring future production into full compliance if they are to be exported to the U.S.

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 also respond in writing within 15 days of receipt of this letter under 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.

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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 and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

The following failure to comply with the regulations regarding reports and record keeping may also have occurred:

21 CFR 1002.11: Supplemental report. Our records failed to confirm that a supplemental report has been submitted for a laser pointer model DIY Kit. We note, however that a report dated December 28, 1998 (accession Number 9612054-31), submitted by Limate did contain a reference to a red laser pointer model DIY-XXX. However, the report failed to provide any details about this product. Since design and user instructions for a product offered in kit form are significantly different than for a finished product a complete supplemental product report is required for this product. Please refer to the enclosed Laser Notice # 13 for guidance.

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 this product 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 96212. If you have further questions on these requirements, please contact Frank W. Mackison of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,



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

Enc: Laser Notice 13
Web site printout

cc: Ernest Davis
Lasermate Corporation
1977 W. Holt Ave.
Pomona, CA 91768
Fax. (909) 868-0948