



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

AUG 11 1998

WARNING LETTER

Ref:OC:I1-1793

via FEDERAL EXPRESS

Mr. Jeff Lai, Manager  
Yow Tech Electronic Co., Ltd.  
2F. No.15, Min Sheng Rd.  
Hsintien, Taipei Hsien  
TAIWAN

Dear Mr. Lai:

This letter is written to advise you of items of noncompliance with the Federal performance standard for laser products encountered during a review by the United States (U. S.) Customs Service of a shipment of products manufactured by your firm. The products were laser pointers being imported by Idea International Inc., 13111 Brooks Drive, Units E & F, Baldwin Park, CA 91706. The following items of noncompliance were observed:

1. 21 CFR 1010.2 Certification: The products failed to have certification labels as required by this section.
2. 21 CFR 1010.3 Identification: The products failed to have identification labels as required by this section.
3. 21 CFR 1040.10(g)(2) Labeling: The products failed to have permanently affixed to them warning labels such as the Class IIIa warning logotype as required by this section.
4. 21 CFR 1040.10(g)(5) Aperture label: The products failed to have permanently affixed aperture labels as required by this section.

We understand that these products have been refused entry into the U. S. Therefore, we will not require the submission of a notification or a corrective action plan (CAP) for this particular shipment.

However, for any similar noncompliant laser products 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), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) requires the submission of notifications (21 CFR 1003, 1004) and prohibits any manufacturer from the certifying or introducing into commerce, and the importation of 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 under one of the options listed below. In your response you must also provide the number of the products which have been exported to the U.S. In addition, if the product distribution was confined to specific geographical areas of the U. S., 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 and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

A review of our records indicates that we have not received an annual report from your firm for the current reporting period beginning July 1, 1997. This report is required by 21 CFR 1002.11 to be submitted by not later than September 1 of each year. Please submit this report at the earliest opportunity.

Based on the noncompliances cited above, it is clear that Yow Tech Electronic Co. Ltd., has failed to establish and maintain a quality assurance and testing program that assures compliance of your laser products with the standard. Therefore, by this letter, the Center for Devices and Radiological Health (CDRH), and the FDA disapproves the quality control and testing program for all laser products produced for or by Yow Tech Electronic Co. Ltd. This action is taken under the Act.

This disapproval means that your firm is prohibited by Sections 534(h) and 538 of the Act from:

1. Certifying the electronic products manufactured under the disapproved testing program;
2. Introducing or importing products into the U.S. commerce which bear false or misleading certification, that is, products certified under the testing program which has been disapproved, and
3. Introducing or importing into U.S. commerce any products which does not have a certification label permanently affixed to the product, as required by 21 CFR 1010.2.

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Under Section 536(a) of the Act, the CDRH is required to refuse entry or importation into the U.S. of any electronic products if it appears that the product fails to comply with the applicable standard, or the manufacturer's testing program has been disapproved.

To resolve this matter, you must submit all information required under 21 CFR 1002.10 so that the CDRH can determine that your company(s) is in compliance with the Act, that the subject products comply with the performance standard, and that the testing program is in accord with good manufacturing practices.

**The CDRH will advise you whether your submittal is satisfactory.**

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, San Francisco District Office, Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502. 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

CC: Importer: Idea International, Inc.  
13111 Brooks Drive. Units E & F  
Baldwin Park, CA 91706

Shipper: Dana Goods International Co.,  
Taipei World Trade Center, Rm. 3F20  
No. 5, Sec. 5  
Hsin-Yi Rd. Taipei  
TAIWAN