



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

HFI - 35

127451

JUN 16 1999

WARNING LETTER

Ref: OC: I1-1827

via FEDERAL EXPRESS

Visualtek Technology Co., Ltd.
No. 6-26 S. Kao Shan-Ting
Yang-Mei, Tao-Yuan
Taiwan
R.O.C.

Mr. Wei-Chun Chang
Vice Chief Engineering
Tah Chung Steel Corporation
No. 6-26, S. Kao Shan-Ting
Yang-Mei, Tao-Yuan
Taiwan
R.O.C.

Gentlemen:

This letter is to advise you of items of noncompliance with the Federal performance standard for laser products, 21 CFR 1040.10 and 1040.11 encountered during laboratory testing of the radiation output and the labeling of twelve (12) key chain style laser pointers. These pointers were collected from a shipment of pointers consigned to TC International 13225 Barton Circle, Whittier, CA 90605. Shipping documents (copies enclosed) for these pointers identified them as models TA-02 and TA-04. Labeling affixed to the pointers included the number 9710445 and identified the manufacturer as Tah Chung Steel Corporation, No. 6-26 S. Kao Shan-Ting, Yang-Mei, Taiwan, R.O.C. Our records show that this number was assigned to a report submitted by Tah Chung Steel Corporation for laser pointers including a model TA-02X. We also note that Mr. Sam. C. H. Chao, Deputy Manager, Visualtek Technology Co., Ltd., at the address 11F-4, No. 421 Song Shan Rd., Taipei, Taiwan, R.O.C. submitted a product report (accession No. 9812312-00) for laser pointers having the same model designations as are in the report from Tah Chung Steel Corporation report. Please explain the relationship, if any, between these two firms.

The following items of noncompliance were noted:

1. 21 CFR1040.10(c) and 1040.10(d): Classification of laser products. The output of six units exceeded the Class IIIa limit of 5 mW. As a result, these

models are Class IIIb and failed to comply with the requirements of the standard applicable to Class IIIb laser products.

2. 21 CFR 1040.11(b): Surveying, leveling and alignment laser products. Laser pointers are surveying, leveling and alignment laser products and are limited to the accessible emission limits of Class IIIa.
3. 21 CFR 1040.10(g): Labeling requirements. The warning logotype label affixed to the pointer contained incorrect information in position 3 of this label in that the class designation was given as Class II rather than Class IIIa, the intended class of these pointers. Since all units exceeded 1 mW, the intended class designation would be Class IIIa for products having a maximum output of 5 mW. Also, the printing on the label was virtually unreadable due to the small print size. The printing on warning labels must be of sufficient size that can be read without magnification by a person with normally corrected vision.
4. 21 CFR 1040.10(h)(1): User information. The user instructions are conflicting and lack sufficient information to warn the user of the hazards associated with misuse of laser pointers. The statement, "Point at Whatever You Want", printed on the package is inappropriate when the emitted beam could be harmful to the eye if it were to be viewed directly or from a highly reflective mirror surface. As a minimum, user instruction must specifically warn the user not to look into the beam, not to point the beam at people or places where people may be. Pointers are not toys and should only be used by children while under adult supervision.
5. 21 CFR 104.10(h)(1)(ii): User Information. The user instructions failed to include an accurate statement of the output power as required by this paragraph. Listing on the package of multiple wavelengths and output powers in the user instructions and not specifically designating which relate to the actual product in the package is confusing to the purchaser.
6. 21 CFR 1040.10(h)(1)(iii): User information. The user information failed to designate the corresponding position of each label affixed to the pointers.
7. 21 CFR 1040.10(h)(1)(iv): User information. The user instructions failed to include the "Caution -Use of Controls..." statement required by this paragraph.

We understand that these products were refused entry and were not introduced into commerce in the United States. Therefore, we will not require submission of notification or a corrective action plan (CAP) for that particular shipment.

However, 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) 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.

Based on the noncompliances cited above, it is clear that the manufacturer of these laser products has failed to establish and maintain a quality assurance and testing program that assures compliance of laser products with the standard. Therefore, by this letter, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration disapproves the quality control and testing program for all laser products produced by or for Visualtek Technology Co., Ltd. and Tah Chung Steel Corporation. This action is taken under authority of the Act.

This disapproval means that your firms are 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 laser products into the United States commerce which bear false and misleading certification, that is products certified under the testing program which has been disapproved, and
3. Introducing or importing into U.S. commerce any product, which does not have a certification label permanently affixed to the product as required by 21 CFR 1010.3.

Under Section 536(a) of the Act, the CDRH is required to refuse entry or importation into the U.S. of any electronic product if it appears that the product fails to comply with the Act, that the subject products do not comply with the performance standard, and the testing program is not in accordance with good manufacturing practices. Therefore we have requested U.S. Customs Service to refuse entry of all laser products identified as being produced for or by either Visualtek Technology Co., Ltd., or Tah Chung Steel Corporation.

If you intend to export laser products to the U.S. in the future, they must be in compliance with the standard. Therefore, to resolve this matter you must submit all the information required under 21 CFR 1002.10 so that CDRH can determine that your companies are in compliance with the Act, that the subjects products comply with the standard and that the testing program(s) are in accord with good manufacturing practices. The CDRH will inform you whether your submittal is satisfactory.

Page 4 – Visualek Technology Co., Ltd. and
Mr. Wei-Chun Chang

Submit your response to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. Should you have any questions on these requirements, please contact Frank 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: Shipping Documents

CC: Mr. John Hsein
TC International
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Whittier, CA 90605

Mr. Sam C.H. Chao
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11F-4, No 421, Song Shan Rd.
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Division of Import Operations (HFC-170)