



MAY 24 2000

WARNING LETTER

Ref:OC:I1-1855

Accession No.: 0010143-00

Via FEDERAL EXPRESS

Professor Longsheng Qian
General Manager
Changchun New Industries
Optoelectronics Technology Co., Ltd.
No. 140 Remin Street
P.O. Box 1024
Changchun 13002
Peoples Republic of China

Dear Professor Qian:

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, encountered during review of your laser product report, accession number 0010143, for the model GLP green laser pointer, Brand Name CNI.

1. 21 CFR 1040.10(c) and (d) and 21 CFR 1040.11(b). The Green Laser Pointer GLP-05-B, Number 90901813, exceeds the limits of Class IIIa, applicable to surveying, leveling, and alignment laser products.

The information supplied in Attachment 6.1, part II, Measurement and Calculation of pulsed operation, demonstrates that at least unit number 90901813 exceeded the limits of its Class (Class IIIa).

You measured an average power of 2.48 mW in a pulse train with a pulse period of 0.748 ms and pulse width of 0.296 ms. Based on these measurements you determined that the single pulse energy is 1.85 microjoules which corresponds to a peak power of 6.27 mW.

However, if the Class IIIa limit for a 0.296 ms pulse is calculated, the limit for any duration less than 0.39 ms is the same as for Class I and for this pulse width uses the formula: $7 * 10^{-4} * (0.296 * 10^{-3})^{0.75} = 1.58$ microjoules and the corresponding peak power is 5.33 mW.

Clearly the values determined by your measurements are in excess of those limits, so this unit fails to meet its class limits.

In addition, the table presented in the Test Results section on Page 8 is confusing. The table shows values for four different units, while the introductory sentence preceding the table describing its contents only identifies three units having been tested. Please clarify this discrepancy.

The report states in attachment 8.1.2, Paragraph C.a., that the Duty Cycle and Operation Current Examination is performed with a regulated DC power supply adjusted to give an output power of 2.8 volts for examination of pointers operating in a pulsed mode. The user instructions state that the operation of the pointer is with 2 AAA batteries of 1.5 volts each for a total of 3.0 volts or 0.2 volts greater than the test procedure. Classification of laser products must be based upon test procedures where all controls and adjustments listed in the operational, maintenance or service instructions adjusted in combination to result in the maximum accessible emission level of radiation. Clearly a 0.2 volt increase could materially increase the output power of the pointers in both pulsed and continuous mode. Therefore, you should review your measurement procedures to ensure they are the same as are required by the standard at 21 CFR 1040.10(e).

2. 21 CFR 1040.10(g)(4). Radiation output information on warning logotype. The warning logotype failed to include the pulse characteristics of the product. When the product operates in a pulse mode, this information is also required to be included on this label in addition to the maximum output of laser radiation.
3. 21 CFR 1040.10(h)(1)(iii). Label reproduction. The sales literature supplied as attachment 4.2 failed to include a reproduction of the warning logotype affixed to the pointer as required by this section.

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.

Since we are not aware of any of these pointers having been distributed in the United States, you are not being requested to submit a formal corrective action plan at this time; however, all future production must comply with the standard. Persons failing to correct violations may be subject to regulatory action. If you feel that the alleged failures to comply do not exist, you may present your views and evidence within 15 days of receipt of this letter.

You must respond to each of the items listed above stating what actions you will take or what changes you will make to your products to bring future production into full compliance. Your response should be submitted as a supplement to your report within 15 days of receipt of this letter, clearly referencing the accession number given above.

However, if any of these pointers have been distributed in the U.S., 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 been distributed in 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.

Page 4 – Mr. Longsheng Qian

- 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.

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, Minneapolis District Office, Food and Drug Administration, 240 Hennepin Avenue, Minneapolis, Minnesota. 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: Dean DeHarpport
67890 Vermar Terrace
Eden Prairie, MN 55346