



APR 6 2004

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

FEDERAL EXPRESS

WARNING LETTER

Professor Longsheng Qian
General Manager
Changchun New Industries
Optoelectronics Technology Co., Ltd.
No. 6142 Remin Street
Changchun 130022
P. R. China

Ref:OC: I1-1956

Dear Professor Qian:

This letter is to advise you of items of noncompliance with **the Federal laser product performance standard**, encountered during review of the laser product report (0322677-00) for Model CNI GLP-III, Class IIIb diode-pumped all solid state green laser pointer submitted on December 10, 2003. The following items of noncompliance with the Federal regulations concerning electronic products, including the performance standard for Laser products at 21 CFR 1040.10 and 1040.11 were noted:

1. 21 CFR 1040.10(f)(3): Remote interlock connector. The product failed to incorporate a remote interlock connector as required by this section.
2. 21 CFR 1040.10(f)(5)(ii): Laser radiation emission indicator. The product failed to include a provision for delay of emission following initiation of the emission indicator as required by this section.
3. 21 CFR 1005.25: Service of process on manufacturer. The report failed to designate a permanent resident of the United States as the manufacturer's agent upon whom processes, notices orders, etc., may be served as required by this section.
4. 21 CFR 1010.3 (a)(2)(ii): Identification. The identification label failed to include the month and year of manufacturer as required by the section.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), 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 failing to establish and maintain required records or to submit required reports. Failure to respond to this letter can result in FDA initiating regulatory actions. 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 working days of receipt of this letter to one of the options listed below. In your response you must 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 in accordance with 21 CFR § 1103.11(a)(3) to establish that the alleged failures to comply do not exist or do not relate to safety of use of the product. Should you choose to refute the allegations of noncompliance, you will have an opportunity to request a hearing under 21 CFR Part 16.
2. Exemption Request - You may request an exemption from user and dealer/distributor notification under 21 CFR § 1003.30(b). 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 at no charge to the user.
 - a. Notification Letter - Requirements for preparation of notification letters are described 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.

In addition to the above we have the following comments and request for additional information.

1. Laser pointers are class IIIa laser products subject to a maximum output of 5mw in accordance with the requirement of 21 CFR 1040.11(b). Your product, as described in the laser product report (0322677-00), is a class IIIb product. It is not clear from the information you submitted what the maximum output of your product is. In various places, the report says it either has a maximum output of 20mw or 200mw. In either case, this output exceeds the allowable output for a Class IIIa laser product. Class IIIb laser systems are appropriate for industrial, research or laboratory use but not as laser pointers. Accordingly the model GLP-III may not be sold for use as a laser pointer
2. Please describe the key switch and illustrate how it is non-removable when in the on position. The specification sheet included as part of Attachment 4.2 to the report states the key switch on the model GLP-III is optional. A key switch on Class IIIb laser systems is not an option for the product to be in compliance with the standard. Please explain the intent of this statement.

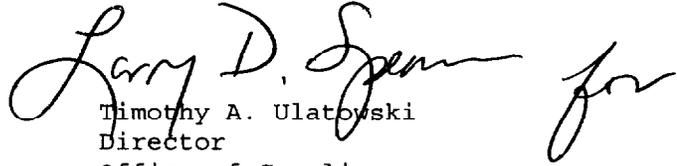
When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

Your response should be sent to: Director, Division of Enforcement B (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,

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New England District Office, Food and Drug Administration, One Montvale Avenue 4th Floor, Stoneham, MA 02180. If you have further questions on these requirements, please contact Frank Mackison of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Larry D. Spenn for". The signature is written in black ink and is positioned to the left of the typed name and title.

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health