



FEB 26 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850WARNING LETTER

Ref: OC: II-1815

via FEDERAL EXPRESS

Mr. William Burgess  
Quality Assurance Manager  
Power Technology Incorporated  
7925 Mabelvale Cutoff  
Mabelvale, Arkansas 72103

Dear Mr. Burgess:

This letter is written to advise you of violations of the Federal Food, Drug, and Cosmetic Act (the Act) and items of noncompliance with the Federal Performance Standard for Laser Products, and the reporting requirements. These violations were encountered during the inspection performed on December 4, 1998, by Dennis Butcher, Electro-Optic Specialist, Southeast Region concerning the Laser Compact Moscow (LCM) CW, series 532nm and 1064nm Class IIIb laser heads; the Laboratory Style DTL series 532nm, 1064nm, 1319nm, and 1340nm CW lasers; the 532nm and 1064nm Q-switched lasers; and model GP-2, Class II 532nm laser pointer.

1. Section 538(a) of the Act and 21 CFR 1010.2. Model LCM-T lasers. Power Technology Incorporated has introduced uncertified model LCM-T Class IIIb, 1064nm laser heads into commerce. Based on a review of the your sales history report dated December 04, 1998, [REDACTED] LCM-T laser heads were sold to [REDACTED] different end users including universities and research facilities.
2. 21 CFR 1040.10(f)(4). The model DTL-031-001 Class IIIb, diode pumped Nd:YAG laser system manufactured in 1994, failed to have a compliant key control. The key is removable in the "on" position with the laser operating.
3. 21 CFR 1040.10(c)(1). Model LP-1M laser pointer. Based on a review of your report (Accession Number 9421404) for the model LP-1M, two milliwatt 532nm laser pointer, and other test measurements made on a Lasex model LP-1M diode pumped frequency doubled Nd:YAG one milliwatt, 532nm laser, your product at minimum exceeds the Class I single pulse limit by a factor of 2.5 times (for pulse shorter than 0.2 microseconds). The Class IIIa single pulse limit is 0.2 microjoules and the measured energy was 0.5 microjoules. There is no specific pulse duration or peak power data in your report for the model LP-1M laser pointer to confirm compliance to the standard. The Lasex model LP-1M laser pointer, which was tested at Brooks Air Force Base in Texas, was manufactured by the Laser Centre, JV "Lasex" Moscow Institute

of Physics and Technology, Dolgoprudny, Institutsky per 9, 141700 Moscow Region, Russia. Also, no copies of the warning labels for model LP-1M laser pointer were provided in your report or user information in order to confirm compliance with the standard.

4. 21 CFR 1040.10(f)(3), 21 CFR 1040.10(f)(6) & 21 CFR 1040.10(g)(2)(iii). Model LP-2M diode pumped laser. After reviewing your report supplement for model LP-2M Diode pumped 10 milliwatt, 532 nm Nd:YAG Class IIIb laser, it was determined that your product failed to have a remote interlock connector, an adequate beam attenuator, and the correct text for the warning logotype. The correct text for position 1 of the warning logotype is "LASER RADIATION-AVOID DIRECT EXPOSURE TO BEAM." The laser notice on beam attenuators and emission indicators dated June 7, 1993, only applies to Class II and Class IIIa laser systems.

Section 538(a) of the Act, Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying, importing 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.

Given the serious nature of these violations of the Act and the Federal Performance standard for laser products, the LCM-T Class IIIb laser heads, the LP-1M and the GP-2 laser pointers and LP-2M lasers imported by Power Technologies Incorporated and manufactured by Laser-Compact Co., Ltd., Moscow, Russia or any other laser product manufactured by the latter may be detained upon entry into the United States (U.S.) until these violations are corrected.

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 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 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(c) 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 was observed: 21 CFR 1002.10 and 1002.11. Our records do not indicate that Power Technologies Incorporated, has submitted reports for the following products:

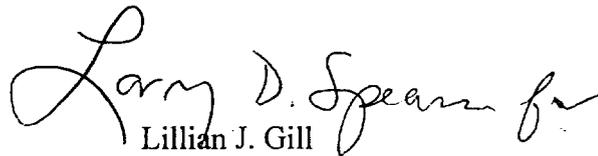
- a. GP-2 Nd:YAG laser pointer
- b. DY series Nd:YAG lasers
- c. DYH series Nd:YAG lasers
- d. T-Series low cost lasers
- e. Laser Simulator model CS 210
- f. Laser Communication System model LCT1

Page 4 – Mr. William Burgess

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, Dallas District Office, Food and Drug Administration, 3310 Live Oak Street, Dallas, Texas 75204. If you have further questions on these requirements, please contact Manuel Karos of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

A handwritten signature in cursive script that reads "Lillian J. Gill".

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

cc: Laser-Compact Co., Ltd.  
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Russia  
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