DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

M5198 HFI 35 Jungst

FEB 5 2001

WARNING LETTER

Ref:OC:I1-1884

via FEDERAL EXPRESS

Mr. Frederick M. Schule
Vice President/General Manager
Lowell Products Development
3815 124th Street, NE
Marysville, Washington 98271

Dear Mr. Schule:

This letter is written to advise you of items of noncompliance with the Federal radiological health regulations and the conditions of your variance, Number 96V-0168. The items below were discovered during a Food and Drug Administration (FDA) inspection of Lowell Products Development by Gary L. Zaharek, Pacific Region Electro-Optics Specialist, on October 20, 2000.

1. Condition 5 of Attachment A of your variance specifically states that "scanning, projection, or reflection of laser and collateral radiation (light show radiation) into audience or other accessible uncontrolled areas shall not be permitted." Condition 6 of Attachment A of your variance further states that audience access to laser radiation exceeding the limits of Class I will be prevented below a height of 3.0 meters and within 2.5 meters lateral separation. It was observed during the inspection that five (5) projectors were being used to perform a Class IIIb laser light show. During the show, laser radiation exceeding the limits of Class I was seen terminating on a wall opposite the display booth and was striking passers-by in the face, chest, and arms. This practice is in violation of Conditions 5 and 6 of Attachment A of your variance.

The item below is also cited due to a trade complaint received on January 2, 2001.

2. Condition 4 of Attachment A of your variance states that laser projection systems and light shows manufactured, assembled, produced, or distributed under your variance shall not be transferred to any other party until the recipient has demonstrated that they have a variance in effect that permits them to produce certified laser light shows incorporating your laser projection systems. On January 2, 2001 a complaint was received indicating that you may have distributed and sold laser light show projectors to customers without approved variances. A similar trade complaint was received by this office last year indicating that Lowell Products Development had sold a projector to a customer without a variance. This issue was brought to your attention in a letter dated June 27, 2000 from this office, for which no response has been received. This practice is in violation of Condition 4 of Attachment A of your variance.

The following failures to comply with the regulations covering records and reports are also noted:

3. 21 CFR 1002.10 and 1002.11 require that all laser product manufacturers submit product and/or supplemental reports, as appropriate, prior to introduction of that product into U.S. commerce. Condition 2 of Attachment A of your variance also requires all laser products, systems, shows, and projectors to be reported as required by 21 CFR 1002.10 and 1002.11. It was observed during the inspection that two (2) foil cross lasers (manufactured by MAP Lighting Engineering of Italy), two (2) LPD Q-Beam 4.95mW projectors, and one (1) LPD Q-40 RG 40mW projector were being used during the show. Product and/or supplemental reports describing these projectors have not been received by this office to date. This practice is in violation of the reporting requirements described in 21 CFR 1002 and Condition 2 of Attachment A of your variance.

4. 21 CFR 1010.4 requires that all variance holders apply for amendments to their variance when changes occur that may affect radiation protection. None of the projectors observed to be in use during the inspection, including the foil cross, LPD Q-Beam, and LPD Q-40 laser projectors, are listed on your variance. This practice is in violation of 21 CFR 1010.4.

5. Condition 4 of Attachment A of your variance specifies that any customer's variance number and effective date shall be entered and retained in your records of compliance test results, as required by 21 CFR 1002.30. 21 CFR 1002.30(2) requires that records of the test results for electronic product radiation safety be established and maintained. The trade complaints indicate that your records of compliance test results lack the necessary data verifing that your customers have approved variances prior to delivery. This practice is in violation of Condition 4 of Attachment A of your variance and recordkeeping requirements specified in 21 CFR 1002.

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. The production or performance of a laser light show is considered to be an act of manufacturing. 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.

You must respond to each of the items listed above stating what actions you will take and what changes you will make to your procedures, equipment, or shows to achieve full compliance. You are also requested to provide information on all customers to which you have sold projectors in the past five (5) years. The information must include the firm name, address, and phone number, and must also indicate the number and effective date of the customer variance and date of sale of the projector. Your response should be submitted within 15 days of receipt of this letter, clearly indicating the reference number provided on this letter.

You are also advised that your variance terminates on May 30, 2001. Your variance will not be considered for renewal until an adequate response to each of the items in this letter has been received.

You are not being requested to submit a formal corrective action plan at this time for distributed products, however, all of your equipment and future performances or distributions must comply with the Federal performance standard and the conditions of your variance. Persons failing to correct violations may be subject to regulatory action. If you feel that the alleged failure to comply does not exist, you may present your views and evidence within 15 days of receipt of this letter.

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 regarding these requirements, please contact LT Sean M. Boyd of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health