



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Michael Van Uum  
Director of Operations  
Moda Company, LLC  
1869 West 25th Street  
Cleveland, Ohio 44113

Ref:OC:I1-1943

Dear Mr. Van Uum:

This letter is to advise you of your company's violations of Federal regulations on laser products and to request a response from you. The violations were discovered during a Food and Drug Administration (FDA) inspection of the Moda nightclub located at 1869 West 25th Street, Cleveland, Ohio, conducted by the FDA Central Region Electro-Optics Specialist, Mr. James Frye, on April 10, 2003. The violations include the following:

1. **Producing laser light shows without an approved variance.**

The regulation at Section 1040.11(c), Title 21, Code of Federal Regulations (21 CFR 1040.11(c)) requires that all demonstration laser products comply with all of the applicable requirements of 21 CFR 1040.10 for Class I, IIa, II, or IIIa laser products and do not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, II, or IIIa. Otherwise, an approved variance from the requirements of 21 CFR 1040.11(c) is needed under 21 CFR 1010.4 for demonstration laser products, including laser projectors and laser light shows, that do not meet the requirements of 21 CFR 1040.11(c).

The inspection revealed that your company assembled and produced laser light shows incorporating a laser projector. Such assembling and production activities render your company a manufacturer of laser products as that term is defined at 21 CFR 1000.3(n). Your laser light show and the incorporated laser projector do not meet the requirements of 21 CFR 1040.11(c), in that they permit human access to laser radiation in excess of the accessible emission limits of Class IIIa. Furthermore, your company produces laser light shows without an approved variance from FDA as required under 21 CFR 1010.4.

To apply for a variance under 21 CFR 1010.4, you must follow the procedures and submit the documents described in that section. The other information indicated at 21 CFR 1010.4(b)(1)(viii) includes the product reports required by 21 CFR 1002.10 for the laser light show and for its projection system. During the inspection, you agreed to immediately cease producing laser light shows with the projection system. You must submit the product reports and variance application, and obtain a variance approval letter from the FDA,

before you can legally perform any laser light shows. Reporting guides for preparing your product reports and the variance application form may be obtained from the following FDA web site:

[http://www.fda.gov/cdrh/comp/rad\\_nonion\\_products.html](http://www.fda.gov/cdrh/comp/rad_nonion_products.html).

## **2. Failure to certify and properly label laser equipment**

The regulation at 21 CFR Part 1010 requires that all electronic products, in this case laser products, be certified as compliant with the applicable Federal performance standards. The product manufacturer must certify compliance with applicable standards based on a testing program to ensure radiation safety. Certification is indicated by a certification label that is permanently affixed to the laser product. In addition, the regulation at 21 CFR 1040.10 addressing the performance standards for laser products requires certain labels.

The inspection revealed that your laser projector did not have the following required certification and other applicable labels:

- (a) certification label required by 21 CFR 1010.2,
- (b) identification label required by 21 CFR 1010.3,
- (c) warning logotype label required by 21 CFR 1040.10(g)(1) through 1040.10(g)(4),
- (d) aperture label(s) required by 21 CFR 1040.10(g)(5), and
- (e) protective housing label(s) required by 21 CFR 1040.10(g)(6) and 1040.10(g)(7).

Because an operator for the laser projector was not available during this inspection, the FDA inspector could not confirm that your laser projector provided the following required performance features:

- (a) safety interlocks as required by 21 CFR 1040.10(f)(2),
- (b) remote interlock connector as required by 21 CFR 1040.10(f)(3),
- (c) key control as required by 21 CFR 1040.10(f)(4),
- (d) emission indicators as required by 21 CFR 1040.10(f)(5) for both the laser projectors and the control panels,
- (e) beam attenuator as required by 21 CFR 1040.10(f)(6),
- (f) scanning safeguard as required by 21 CFR 1040.10(f)(9), and
- (g) manual reset mechanism as required by 21 CFR 1040.10(f)(10).

## **3. Failure to maintain proper records**

The regulation at 21 CFR 1002.30 requires that all laser product manufacturers maintain records of quality control procedures, results of radiation safety testing, copies of written communications concerning radiation safety, and production and distribution records. During the inspection, your company was not able to provide any of these required records.

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 failing 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 Section 538(a)(4) of the Act. The 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 Section 538 are subject to civil penalties of up to \$1,000 per violation and up to a maximum penalty of \$300,000.

You are required to respond to this letter. You may not conduct additional laser light shows until the required documentation is submitted to FDA and you are granted a variance to perform laser light shows.

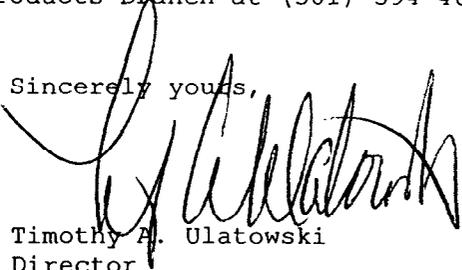
In addition, we also have several questions concerning the projection system that require your response.

- Who is the provider of the laser equipment used in the Moda Nightclub? Please provide the firm name, contact name, address, and the phone number(s) of the firm and responsible individual.
- When did you first rent the equipment from the provider?
- How long have you produced shows with the equipment?
- What are the output characteristics (power, wavelength, pulse rate, etc.) of the laser contained in the projection equipment?

Please submit the reports and variance application, and respond to each of the items listed above. Please clearly identify what actions you will take and what changes you will make to your equipment or shows to achieve full compliance. If you feel that the alleged failures to comply do not exist, you may present your views and evidence in your response.

Your response should be submitted within 15 working days of receipt of this letter. You should clearly indicate the reference number found at the top of this letter, and send the response 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, Cincinnati District Office, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237.** If you have further questions regarding these requirements, please contact Dale Smith of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,



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