



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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OCT 29 1997

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

WARNING LETTER

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Ref:OC:I1-1765

Mr. Martin Canavan  
President  
YLS Productions  
P.O. Box 34  
Los Alamitos, California 90720

Dear Mr. Canavan:

This letter is written to advise you of items of noncompliance with the Federal laser performance standard and your variance No. 91V-0150. The noncompliances were encountered during an inspection of the projection equipment and performance of the laser show at the Magic Mountain Theater on July 29, 1997. The inspection was conducted by Frank W. Mackison, Consumer Safety Office, Office of Compliance accompanied by Ms. Cynthia Faville and Ms. Susan Jensen.

1. 21 CFR 1040.10(g)(4) Labeling requirements. The warning logotype affixed to the projector failed to include the laser output information in position 2 as required by this paragraph.
2. 21 CFR 1040.10(f)(1) Protective housing. The protective housing or projector cover contained a gap between the cover itself and the optics table which it covered thereby permitting possible unnecessary access to laser radiation in excess of Class I.
3. Variance No. 91V-1050, Attachment A Paragraph 6. During the inspection a beam alignment check was conducted. During this alignment check operators were observed to walk unnecessarily and causally through the projected beams estimated to be in excess of Class II.

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.

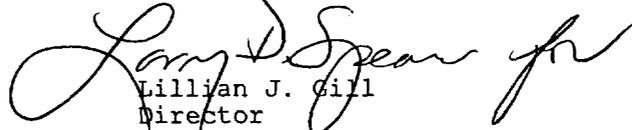
You are not being requested to submit a formal corrective action plan at this time, however, all of your equipment and future performances must comply with the Federal performance standard/variance. Persons failing to correct violations may be subject to regulatory action. If you feel that the alleged failures to comply do not exist, you may present your views and

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You must respond to each of the items listed above stating what actions you will take and what changes you will make to your equipment or shows to achieve full compliance. Your response should be submitted as a supplement to your report within 15 days of receipt of this letter, clearly referencing the appropriate accession number.

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, Los Angeles District Office, Food and Drug Administration, 19900 MacArthur Boulevard, Irvine, California 92715. If you have further questions regarding these requirements, please contact Frank W. Mackison of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill".

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