



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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11/8/98

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DEC 11 1997

WARNING LETTER

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

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Ref:OC:I1-1767

Mr. Gary M. Kristan  
Works Theater Coordinator  
The Carnegie Science Center  
One Allegheny Avenue  
Pittsburgh, Pennsylvania 15212-5850

Dear Mr. Kristan:

This letter is written to advise you of an item of noncompliance with the Federal performance standard for laser products encountered during a review of the 1997 annual report submitted by Carnegie Science Center, dated August 14, 1997.

21 CFR 1040.11(c). Based on our report review, the Center for Devices and Radiological Health has determined that your company manufactured laser light shows which permit human access to laser radiation in excess of Class IIIa after your variance, number 91V-0363, expired on September 23, 1996.

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 \$1,000.00 per violation and up to a maximum penalty of \$300,000 without further notification by the FDA.

If you feel that the alleged noncompliance does not exist, you may present your views and evidence within 15 days of receipt of this letter.

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You must respond to the item 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 91A1124.

Your response should be sent to: Director, Division of Enforcement III (HFZ-342), 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, Philadelphia District Office, Food and Drug Administration, (HFR-MA100), 900 US Customhouse, 2<sup>nd</sup> & Chestnut Sts., Philadelphia, PA 19106. If you have further questions regarding these requirements, please contact Cynthia Faville of the Electronic Products Branch at (301) 594-4654 extension 142.

Sincerely yours,



Lillian J. Gill

Director

Office of Compliance

Center for Devices and

Radiological Health