HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M2009N

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 3 1998

WARNING LETTER

Ref:OC:I1-1806

via FEDERAL EXPRESS

Mr. Jack A. Dunn
Planetarium Coordinator
Mueller Planetarium
University of Nebraska Lincoln
213 Morrill Hall
Lincoln, Nebraska 68588

Dear Mr. Dunn:

This letter is written to advise you of items of noncompliance with the laser product performance standard, the regulations, and conditions of a variance encountered during a Food and Drug Administration inspection of your facility and laser light show by Dennis Butcher on September 25-29, 1998.

1. 21 CFR 1010.2. The laser projector and laser light show did not have a certification label(s) present as required.

2. 21 CFR 1010.3. The laser projector and laser light show did not have an identification label(s) present as required.

3. 21 CFR 1040.10(g)(3). The Class IV warning logotype on the projector had an incorrect (Class IIIb) warning statement.

4. 21 CFR 1040.10(g)(3). The Class IV laser projector had two Class IIIb warning logotypes placed on a side panel and on the top cover.

5. 21 CFR 1040.10(g)(5). A label was present on the front aperture panel which contained the warning "CAUTION Laser Radiation Do Not Stare Into Beam" which is only appropriate for Class II laser light emissions.

6. 21 CFR 1040.10(g)(5). The aperture labels on the projector did not give the warning as required.

7. 21 CFR 1040.10(g)(6). The noninterlocked protective housing labels as modified to recognize the presence of non-safety interlocks were not visible after removal of the projector cover panels.

8. 21 CFR 1040.11(c). The variance (Number 94V-0346) previously held by your firm had expired on November 14, 1996, and the laser light show emission levels did exceed the limits of Class IIIa.

9. 21 CFR 1040.11(c) and Condition 6, Variance No. 94V-0346. Further, even if Variance No. 94V-0346 had been in effect, your laser emissions failed to satisfy the separation distances required under Condition 6 of that variance in at least three areas within the public theater.

The following failures to comply with the regulations covering records and reports were observed:

1. 21 CFR 1002.30(a)(1). The written procedures for compliance checks of the laser display and the projector failed to describe tests to assure compliance of the following: product labeling, system protective housing, system remote interlock connector, system key control, system emission indicators, system manual reset mechanism, projector physical masking, and audience/laser light separation.

2. 21 CFR 1002.30(a)(2). The compliance test records do not demonstrate that compliance tests of at least the above listed items have been conducted.

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 evidence within 15 days of receipt of this letter.

We have received your response of October 8, 1998, addressing the above items and requesting renewal/amendment of your variance and providing a product report on the Mueller Planetarium laser projector MP-007. We have reviewed this information and have no further questions at this time. Note that the request for renewal and amendment of your variance is being handled by a separate letter.

Thank you for your attention to this matter.

If you have further questions regarding these requirements, please contact Dale Smith of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

Larry D. Spears for

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