



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MADON

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

WARNING LETTER

Ref: OC: II-1800

SEP 10 1998

via Federal Express

Mr. Dave Leavenworth  
Entertainment Technical Productions  
Knott's Berry Farm  
8039 Beach Blvd.  
Buena Park, California 90620

Dear Mr. Leavenworth:

This letter is written to advise you of items of noncompliance with the Federal performance standard for laser products and your laser light show variances at Knott's Berry Farm. The noncompliances were encountered during an inspection of the equipment and performances of the laser light show at the Good Time Theater and the Reflection Lake locations. The inspection was performed on July 17, 1998, by Ms. Serrah Namini, Electro-Optics Specialist, FDA Los Angeles District Office and Mr. Collin Figueroa, Consumer Safety Officer, of this office.

The following items of noncompliance were noted during the inspection:

The "Reflection Lake" outdoor laser light show.

1. 21 CFR 1040.10(f)(1) Protective housing: The front cover of the MR-10WH 330 projector is open, and this could permit human access to laser radiation. On August 14, 1998, you confirmed in writing that an aperture shutter had been installed on July 18, 1998, by Mirage Productions. This correction is not adequate because you either need to build another front panel or move the projector forward to connect it with the current front panel.
2. Variance No. 79V-0257, Attachment A: The laser display exceeded the limits specified in 21 CFR 1040.11(c) and therefore the following observations apply.
  - a. Conditions 4 and 5. Direct and scanned laser beams were emitted from the laser projector toward stationary mirrors, water fountains, trees and designated termination points. Some of the Class IV laser beams were observed to pass their intended termination points, such as trees,

and went into the air. During alignment, there were at least three laser beams that were observed to have missed their termination points. On August 14, 1998, you confirmed in writing that all the laser beams were realigned to hit a suitable nonmoving termination point as discussed in your post-inspection meeting with Ms. Namini and Mr. Figueroa.

- b. Condition 9. The scanned laser effects projected toward the water screen were terminated on a wall across the lake below the 12 ft. vertical height mark. The scanned laser effects were also terminated on the front of the mountain at about 10 ft. vertical height. You and your contractor acknowledged that the beams were below the 3 meter specified height and promised to increase the angle of these effects to bring them into compliance.
- c. Conditions 2 and 3. The laser light show report for the “Reflection Lake” outdoor show and model change report for the MR-10WH 330 projector were not submitted as required by 21 CFR 1002.10 and 1002.12 prior to any introduction into commerce of the laser show.

The “Good Time Theatre” indoor laser light show.

- 3. 21 CFR 1040.10(f)(1). The protective housing for the model TL-32 serial number 326 had gaps along the top panel that would allow unnecessary human access to Class IV laser radiation.
- 4. Variance No. 95V-0251, Attachment A: the laser display exceeded the limits specified in 21 CFR 1040.11(c) and therefore the following observations apply:
  - a. Conditions 3 and 6. The scanned laser cone effect performed at the stage near performers for the Snoopy show was not included in your variance. On August 14, 1998, you confirmed in writing that this effect has been documented and submitted with your 1998 supplemental report and sent to our office on July 25, 1998.
  - b. Condition 7. There was no scan failure safeguard for the scanned laser cone effect. On August 14, 1998, you confirmed in writing that laser interrupt equipment is being researched and you have reiterated performer training instructions. Please note this cone effect is not in

compliance with the conditions of your variance and should be discontinued until an adequate scan failure safeguard can be provided for this effect.

- c. Condition 12. Quality Control Procedures. The “TL-2000 Laser Light Show checklist” failed to include a listing of all the laser beam effects and their termination points. This checklist does not refer to the setting of beam blocks. There were no procedures to show how to position the beam blocks and guide the operator through the alignment process. On August 14, 1998, you confirmed in writing that the operational adjustments have been made to reflect the use of the beam termination checks within the QC process. This effect has been documented and presented in your supplemental report sent to this office on July 25, 1998.

The following observation and recommendation relates to your record keeping procedures.

Although problems encountered in daily operation of the shows are recorded in a log book maintained at each show, there was no convenient way to determine what actions, if any, were taken to correct problems. Problems that occur should be cross-referenced to the actions taken to correct them.

At the conclusion of the inspection, the above items of noncompliance were discussed with you. You stated that all items would be corrected and that you would write to FDA/CDRH regarding your corrections. Please note you still need to address the items of noncompliance in items 1, 2c, 3, and 4b of this letter. Other items of noncompliance may still need to be addressed based on our review of your supplemental report sent to this office on July 25, 1998.

Further, based on our phone conversation on August 13, 1998, and your written confirmation dated August 14, 1998, we understand that Mirage Productions will temporarily provide an operator for the “Reflection Lake” outdoor laser light show and will operate under Mirage’s laser light show variance. The Knott’s Berry Farm variance for the outdoor laser light show will not be amended until adequate corrections are made to your noncompliant laser shows and projection systems and until you submit adequate laser light show and projector reports to this office.

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 performing of a laser light show is an act of manufacturing. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports.

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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 violation 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 and 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 the date of this letter.

You must respond to each of the items listed above stating what action you have taken or will take and what changes you have made or will make to your equipment and shows to achieve full compliance. Your response should be submitted within 15 days of the date of this letter, clearly referencing the appropriate variance number for each show.

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, Suite 300, Irvine, California 92612-2445. If you have any questions regarding this matter, please contact Manuel G. Karos of my staff at (301) 594-4654.

Sincerely yours,



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