HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

...TS MANAGEMENT BRANCH

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Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

MAY 18 1993

Ref: FDA Docket No. 87V-0401
Accession No. 87A2066-03

Mr. John J. Markham
President
Chameleon Productions
6206 Forest City Road, Suite C
Orlando, Florida 32810

Dear Mr. Markham:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Chameleon Productions, dated March 9, 1993, for an amendment to their variance, Number 87V-0401, from 21 CFR 1040.11(c) of the performance standard for laser products is approved. This variance will allow the introduction into commerce of the laser light show products described in paragraph D below.

A. Variance Number

87V-0401

B. Effective Date

In accordance with 21 CFR 1010.4(c)(1), this variance amendment shall become effective on the date of this letter.

C. Termination Date

This variance shall be terminated January 21, 1995.

D. Product for Which Variance is Granted

This variance is granted for the Chameleon Productions laser light shows, such as "Out of the Darkness" and "The Jump Club," incorporating Class IV Precision Projection Systems Model TL24D or Laser Media Models LMS or LM ion laser projection systems. The laser light shows may be presented in any type of location for any contract duration. The laser effects may be front or rear screen projections, holographic displays, multiple reflection/diffraction effects, reflections from stationary mirrors, stationary or scanning irradiation of rotating mirror balls, fiber optic projections, and enhanced scattering effects.

E. Provision from Which Variance is Granted

This variance is granted from 21 CFR 1040.11(c) of the performance standard for laser products requiring that each demonstration laser product shall comply with all of the applicable requirements of 21 CFR 1040.10 for a Class I, IIa, II, or IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, Class II, or Class IIIa.

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F. Conditions under Which Variance is Granted

In lieu of the requirements referred to in Item E above, the conditions as specified below in Variance Attachment A and, if included, Variance Attachment B shall apply to the products and devices manufactured under this variance and to the shows assembled and produced under this variance.

G. Basis for Approval of Variance

In accordance with 21 CFR 1010.4(a)(2), it has been determined that the product is required to perform a necessary function or is intended for a special purpose which cannot be performed or accomplished with equipment meeting the requirements referred to in Item E. Suitable means of radiation safety and protection will be provided by constraints on the physical and optical design, and by warnings in the user/purchaser information.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state: This product complies with performance standards for laser products under 21 CFR Part 1040 except with respect to those characteristics authorized by Variance Number 87V-0401 effective January 21, 1988.

This variance action is available for public disclosure in the Food and Drug Administration (FDA) Dockets Management Branch and a notice of availability will be published in the Federal Register. The variance will remain in effect until the termination date unless a determination is made that the variance should be amended or withdrawn to protect the public health and safety.

Sincerely yours,

for Ronald M. Johnson
Director
Office of Compliance
and Surveillance
Center for Devices and
Radiological Health

cc: FDA Dockets Management Branch, Docket No. 87V-0401

Attachments A and B

Variance Attachment A
Variance No. 87V-0401
CHLE

1. This variance is not transferable to any other firm or person and applies only to the specific products identified in the variance.

2. All laser products, systems, shows, and projectors shall be certified to comply with applicable requirements of 21 CFR 1040.10 and the conditions of this variance and be reported as required by 21 CFR 1002.10 and 1002.12 using the reporting guides provided for such purpose. These actions shall be accomplished prior to any introduction into commerce.

3. Effects not specifically indicated in the variance application shall not be performed. Any additional effects require the submission of an amendment request (using Form 3147 or in accordance with 21 CFR 1010.4) and the filing of product reports or supplements as applicable.

4. Scanning, projection, or reflection of laser and collateral radiation (light show radiation) into audience or other accessible uncontrolled areas shall not be permitted except for diffuse reflections produced by the atmosphere, added atmospheric scattering media, and target screens.

5. Access to radiation levels in excess of the limits of Class I by any person other than operators, performers, or employees shall not be permitted at any point less than 3.0 meters above any surface upon which such persons are permitted to stand or 2.5 meters below or in lateral separation from any place where such persons are permitted to be. Operators, performers, and employees shall not be required or allowed to view radiation above the limits of Class I or be exposed to radiation above the limits of Class II.

6. Any product which relies on scanning to meet access, exposure, or product class limits shall incorporate a scanning safeguard system which directly senses scanner motion and which will react fast enough to preclude exceeding the applicable limit.

7. All laser light shows shall be under the direct and personal control of a trained, competent operator(s). The operator(s) shall:

   (a) immediately terminate the emission of light show radiation in the event of any unsafe condition;

(b) be located where all beam paths can be directly observed at all times; and

(c) be an employee of the variance holder who shall be responsible for the training and conduct of the operator.

8. The maximum laser projector output power shall not exceed the level required to obtain the intended effects.

9. The projection system (i.e., the projector and all other components used to produce the lighting effects) shall be securely mounted or immobilized to prevent unintended movement or misalignment. Beam masking to prevent projections into prohibited areas or directions or overfilling of screens, beam stops, targets, etc. shall be incorporated as an inherent part of the system design. Such devices may be adjustable if the system's intended use environment requires such capability.

10. In addition to the requirements of 21 CFR 1040.10(h), the manufacturer of laser projectors/systems shall provide to parties who purchase, lease, or borrow the equipment, adequate user's instructions for safe installation and operation. These instructions shall also explain the responsibility of the recipient as an independent light show manufacturer to submit the required reports and apply for and obtain a variance from the Center for Devices and Radiological Health (CDRH) prior to the introduction into commerce of any laser light shows.

11. The requirements of 21 CFR 1002.30(a)(1) and (2) shall be accomplished through the use of written procedures for setup, alignment, testing, and performance of each show. These procedures shall be in sufficient detail to ensure compliance with 21 CFR 1040.10, the conditions of this variance, and the control of access to radiation areas using the procedures described in the ANSI Z136.1-1992 Standard For The Safe Use of Lasers (available from The Laser Institute of America, 1242 Research Parkway, Suite 130, Orlando, Florida 32826) or any other equivalent user consensus standard and, where applicable, State or local requirements.

Laser radiation areas which can contain radiation levels above Class I or II as applicable, shall be clearly identified by the posting of warning signs and/or restricting access through physical means (such as pressure switches, photocells, barriers, guards, etc.). These requirements apply to temporary areas (such as during setup and alignment procedures) and to final or permanent areas.

The variance holder shall retain the records of these procedures and the results of all tests as required by 21 CFR 1002.31. A copy of the variance application, the approval letter, current procedures, and records relating to each particular show shall be with the operator or other responsible individual and shall be made available for inspection by FDA and other responsible authorities.

12. Advance written notification shall be made as early as possible to appropriate Federal, State, and local authorities providing show itinerary with dates and locations clearly and completely identified, and a basic description of proposed effects including a statement of the maximum power output intended. Such notifications shall be made, but not necessarily be limited, to:

    (a) The Center for Devices and Radiological Health (CDRH), Office of Compliance and Surveillance (address below) providing the initial and closing dates for fixed installations and the itinerary for mobile shows. In addition, unless all aspects of each show have been reported and the Accession Number(s) clearly referenced, each notice shall include detailed descriptions of each show and a listing of all effects to be performed in sufficient detail to confirm compliance with the regulations and this variance. To be considered timely, this written notice must be submitted 30 days prior to the opening of the subject show or, when the show becomes known to the manufacturer less than 30 days prior to the show date, the required information must be provided verbally in an immediate phone call to CDRH and also confirmed in the formal written notice that includes the date of the phone notification and the name of the official to whom the information was given.

    (b) The Federal Aviation Administration (FAA) for any projections into open airspace at any time (i.e., including setup, alignment, rehearsals, performances, etc.). If the FAA objects to any laser effects, the objections shall be resolved and any conditions requested by FAA will be adhered to. If these conditions can not be met, the objectionable effects shall be deleted from the show.

    (c) State and local radiation control offices/agencies for all shows to be performed within their jurisdictions. All requirements of State and local law shall be satisfied and any objections raised by local authorities shall be resolved or the effects deleted.

Unless otherwise specified by regulation (e.g., variance applications), all correspondence to be provided to the CDRH shall be addressed to:

Center for Devices and Radiological Health
Office of Compliance and Surveillance (HFZ-312)
1390 Piccard Drive
Rockville, MD 20850
Phone: (301) 427-1172

Variance Attachment B
Variance No. 87V-0401
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This attachment provides the list of information to be provided to the Federal Aviation Administration (FAA) in notifications of outdoor laser light shows (demonstrations) employing projections into the sky. This information is required to permit FAA to do the aeronautical study necessary to determine whether or not the proposed effects are objectionable.

CONTENT OF NOTIFICATIONS

a. Proponent notifications to the FAA regional office will include the following information on all proposed outdoor demonstrations:

(1) Name of laser group/company,

(a) Business address and telephone number,

(b) Variance number and expiration date,

(2) Date(s) and time(s) of show(s),

(3) Date(s) and time(s) of setup and alignment,

(4) Location of show,

(a) Name and address of show venue or site,

(b) Latitude and longitude of show venue or site,

(5) Maximum emitted peak power (Watts) at the projector as reported to the CDRH,

(6) Azimuthal direction of projections,

(7) Elevation of projections in degrees above the horizon,

(8) Beam divergence in milliradians,

(9) Maximum distance from source (slant range) for an irradiance of 2.6 mW/sq.cm based on maximum emitted peak power and divergence.

(10) Maximum altitude above source for an irradiance of 2.6 mW/sq.cm based on maximum emitted peak power, divergence, and elevation angle of projection,

(11) A diagram depicting unterminated beam arrays, if applicable,

(12) Name of laser safety officer/operator,

(a) Local address and phone number,

(13) Additional safety procedures,

(a) Communications procedures during the show,

(b) Visual aircraft spotters,

(c) Other.

b. Supplementary information, if applicable. Include any letter(s) from the CDRH validating the measures which result in a smaller affected zone than that shown by the Laser Projector Power/Range Table of the FAA Airspace Handbook.

SUBMISSION OF PROPOSAL

a. The last condition of Attachment A of the variance requires that you notify the Federal Aviation Administration (FAA) before conducting an outdoor laser light show.

b. In detail, this requirement means that:

(1) All notifications are to be directed to the Air Traffic division at the FAA regional office having jurisdiction over the area where the laser show will take place.

(2) FAA needs at least 21 days advance notice to process a request and conduct an aeronautical study. The FAA recognizes that industry conditions may not always permit the advance notice desired. While FAA endeavors to accommodate all requests, proper conduct of the aeronautical study to determine airspace effects is essential to air safety. This is particularly true when demonstrations are near airports or when the nature of the demonstration would necessitate protection of large amounts of airspace. In these cases, it may be impossible for the FAA to respond favorably to short-notice requests.

(3) Notifications are required for all demonstrations in which projections will be directed or reflected into the navigable airspace (including setup, alignment, and rehearsals). Notifications should contain a minimum of technical information. Of primary concern is the maximum distance from and altitude above the source to be affected by a proposed demonstration.

(4) A proponent wishing to provide supplementary information about measures which will result in a smaller actual danger zone than that shown by the Laser Projector Power/Range Table of the FAA Airspace Handbook should submit the data in advance to CDRH for review. CDRH will evaluate the information and issue a letter to the proponent to include with their notification to FAA.