

Chameleon Productions
500 East Concord St.
Orlando, Florida. 32803
(305) 422-3444

1987 DEC -8 PM 9 21

December 2, 1987

Food and Drug Administration Rm. 4-65
5600 Fishers Lane
Rockville, MD. 20857
Attention: Hearing Clerk

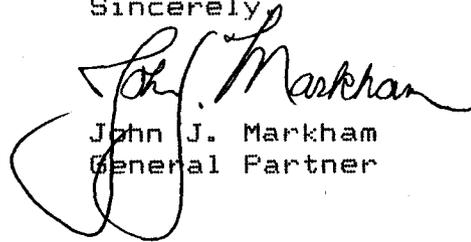
To Whom it May Concern:

This communication is written to inform you that "Chameleon Productions" is submitting an application for a variance for laser light shows. Enclosed please find form FDA 3147.

As a principal designer for "Laser Media, Inc." Los Angeles for the last four years and technical consultant for the 1981 "Laserworld" project in Orlando, Florida, I have had extensive laser production show experience. "Chameleon Productions" assures all performances will be conducted in accordance with the applicable Federal, State, and local laser safety regulations, and with the conditions established in the variances. All laser projection systems used, and all effects planned, will be fully reported in accordance with regulatory requirements and a completed laser light show report has been submitted to the "Office of Compliance" in Silver Springs, Maryland.

Please do not hesitate to contact us with any questions you might have. We welcome your interest and are looking forward to working with the center in the future.

Sincerely,



John J. Markham
General Partner

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11(c) FOR A LASER LIGHT SHOW, DISPLAY OR DEVICE	Form Approved: OMB No. 57R0068 Use of this form is prohibited after July 31, 1984 DOCKET NUMBER
NOTE: No laser light show or display device may vary from compliance with 21 CFR 1040.11(c) in design or use without the approval of this application in accordance with 21 CFR 1010.4.		
INSTRUCTIONS		
1. Check all applicable boxes and type or print the requested information. 2. Submit an original and four (4) copies.	3. Mail your application to the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857. 4. Enter Docket Number if assigned.	
1. NAME OF COMPANY Chameleon Productions		
2. ADDRESS OF COMPANY (Include ZIP Code) 500 E. Concord Street, Orlando, Florida 32803		
3. NAME OF RESPONSIBLE PERSON John Markham / Daniel Markham	4. TELEPHONE NO. (Include area code) (305) 422-3444	5. DATE OF SUBMISSION 12/3/87
6. The applicant requests the variance to be in effect for a period of 2 years from the date of issue and requests to manufacture 1 units under this variance. (In general the Agency will approve a variance for only two years. If a longer period is requested a justification must be attached as part of the application.)		
7. PRODUCT DESCRIPTION AND USE		
a. LIST NAME AND MODEL NUMBER(S) Chameleon Productions Laser Lighting Effects		
b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED <input type="checkbox"/> A LASER DISPLAY DEVICE <input type="checkbox"/> A PROJECTOR FOR A LASER LIGHT SHOW <input checked="" type="checkbox"/> A LASER LIGHT SHOW <input type="checkbox"/> OTHER (Specify)	e. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION <input checked="" type="checkbox"/> MORE THAN 15 DAYS <input checked="" type="checkbox"/> MORE THAN 5 BUT NOT MORE THAN 15 DAYS <input checked="" type="checkbox"/> LESS THAN 5 DAYS	f. TOUR IS INTENDED TO RUN FOR <input checked="" type="checkbox"/> MORE THAN 6 MONTHS <input checked="" type="checkbox"/> 1-6 MONTHS <input checked="" type="checkbox"/> LESS THAN 1 MONTH <input checked="" type="checkbox"/> NOT APPLICABLE (not a tour) <input type="checkbox"/> OTHER (Specify)
c. PRODUCT IS INTENDED FOR USE IN A <input checked="" type="checkbox"/> PLANETARIUM OR OTHER DOME PROJECTION STRUCTURE <input checked="" type="checkbox"/> THEATER <input checked="" type="checkbox"/> DISCOTHEQUE OR NIGHT CLUB <input checked="" type="checkbox"/> PAVILION <input checked="" type="checkbox"/> INDOOR ARENA <input checked="" type="checkbox"/> OUTDOOR ARENA <input checked="" type="checkbox"/> MUSEUM <input checked="" type="checkbox"/> OUTDOOR ENCLOSED AREA <input type="checkbox"/> OTHER (Specify)	g. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS <input checked="" type="checkbox"/> FRONT SCREEN PROJECTIONS <input checked="" type="checkbox"/> REAR SCREEN PROJECTIONS <input checked="" type="checkbox"/> HOLOGRAPHIC DISPLAYS <input checked="" type="checkbox"/> MULTIPLE REFLECTIONS (multiple channel or diffraction effects) <input type="checkbox"/> AUDIENCE SCANNING <input checked="" type="checkbox"/> REFLECTIONS FROM STATIONARY MIRROR(S) OR MIRRORED SURFACES <input checked="" type="checkbox"/> STATIONARY IRRADIATION OF ROTATING MIRROR BALL(S) OR OTHER MIRRORED SHAPES <input checked="" type="checkbox"/> SCANNING IRRADIATION OF ROTATING MIRROR BALL(S) <input checked="" type="checkbox"/> FIBER OPTIC PROJECTIONS <input checked="" type="checkbox"/> FOG, SMOKE OR OTHER SCATTERING EFFECTS <input type="checkbox"/> OTHER (Specify)	
d. PRODUCT IS INTENDED TO BE USED <input checked="" type="checkbox"/> AT ONLY ONE (fixed) LOCATION <input checked="" type="checkbox"/> AT A VARIETY OF (tour) LOCATIONS <input type="checkbox"/> OTHER (Specify)		
8. LASER RADIATION LEVELS		
LASER MEDIUM (Ar, He-Ne, etc.)	WAVELENGTHS (nm)	PEAK POWER (Watts)
Argon Gas	454.5-528.7	20 W
Krypton Gas	476.2-676.4	10 W
HeNe	632.8	5 MW
9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE 20 kHz scan frequency amplitude <60 20 k pulses/sec 50 usec pulsewidth		
10. REASON FOR REQUESTING VARIANCE <input checked="" type="checkbox"/> COMPLIANCE WITH THE LIMITS OF 21 CFR 1040.11(c) WOULD RESTRICT THE INTENDED USE OF THE PRODUCT BECAUSE COMPLIANCE WOULD LIMIT THE OUTPUT POWER TO THE EXTENT THAT THE DESIRED EFFECTS WOULD NOT BE SUFFICIENTLY VISIBLE <input type="checkbox"/> OTHER OR ADDITIONAL EXPLANATION (Specify)		

11. MANNER IN WHICH IT IS PROPOSED TO DEVIATE FROM THE REQUIREMENTS OF THE APPLICABLE STANDARD

- IT IS PROPOSED TO DEVIATE FROM THE PROVISIONS OF 21 CFR 1040.11(c) IN THAT THE ACCESSIBLE EMISSION LEVEL WOULD EXCEED THE ACCESSIBLE EMISSION LIMITS OF CLASS I OR CLASS II
- IT IS PROPOSED TO DEVIATE FROM THE PROVISION OF 21 CFR 1040.11(c) AS FOLLOWS

12. ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION

- LASER LIGHT SHOWS AND DISPLAYS ARE ACCEPTED POPULAR MEDIA IN ENTERTAINMENT AND THE ARTS. USE OF POWER LEVELS IN EXCESS OF THE LIMITS IMPOSED BY 21 CFR 1040.11 (c) IS NECESSARY TO ACHIEVE THE REQUIRED EFFECTS IN THESE MEDIA.
- OTHER OR ADDITIONAL ADVANTAGES (*describe and explain*)

13. EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. (*Check as many boxes, as apply. Explain any boxes not checked using additional sheets as necessary. If appropriate, state any other means of radiation protection that will be used.*)

- a. ALL LASER PRODUCTS, SYSTEMS AND PROJECTORS WILL COMPLY WITH 21 CFR 1040.10 FOR LASER PRODUCTS OF THEIR CLASS (*Specify class(es)*)
- & Class IV
-
- b. LASER AND COLLATERAL RADIATION MEASURED WHERE THE AUDIENCE IS LOCATED, SHALL NOT EXCEED THE LIMITS OF CLASS I DURING OPERATION (*includes reflections from targets and scattering materials*).
- c. OPERATORS, PERFORMERS AND EMPLOYEES WILL BE ABLE TO PERFORM THEIR FUNCTIONS WITHOUT THE NEED TO VIEW LASER AND COLLATERAL RADIATION IN EXCESS OF THE LIMITS OF CLASS I AND WITHOUT BEING EXPOSED TO LASER RADIATION IN EXCESS OF THE LIMITS OF CLASS II. HUMAN EXPOSURE TO CLASS III OR CLASS IV LEVELS OF RADIATION SHALL NOT BE PERMITTED.
- d. SCANNING DEVICES, INCLUDING MIRROR BALLS, WILL INCORPORATE A SCANNING SAFEGUARD TO PREVENT LASER EMISSION IF SCAN FAILURE OR OTHER FAILURE CAUSING A CHANGE IN EITHER SCAN VELOCITY OR AMPLITUDE WOULD RESULT IN VIOLATION OF ITEMS 13b OR 13c.
- e. WHEN LASER LIGHT SHOWS OR DISPLAYS ARE NOT OPERATED AT ALL TIMES UNDER THE DIRECT CONTROL OF AN OPERATOR, LASER RADIATION LEVELS WILL NOT EXCEED THE LIMITS OF CLASS II AT ANY POINT LESS THAN 6 METERS ABOVE ANY SURFACE UPON WHICH A PERSON IN THE AUDIENCE IS PERMITTED TO STAND, OR AT ANY POINT LESS THAN 2.5 METERS IN LATERAL SEPARATION FROM OR BELOW ANY POSITION WHERE A PERSON IN THE AUDIENCE IS PERMITTED DURING THE PERFORMANCE OR DISPLAY. A DESIGNATED PERSON(S) WILL BE RESPONSIBLE, AT ALL TIMES DURING THE SHOW OR DISPLAY, FOR THE IMMEDIATE TERMINATION OF LASER RADIATION IN THE EVENT OF EQUIPMENT MALFUNCTION, AUDIENCE UNRULINESS, OR OTHER UNSAFE CONDITIONS. ONE OR MORE READILY ACCESSIBLE CONTROLS TO EFFECT IMMEDIATE TERMINATION OF LASER RADIATION WILL BE PROVIDED FOR THIS PURPOSE.
- f. WHEN LASER LIGHT SHOWS OR DISPLAYS ARE OPERATED AT ALL TIMES UNDER THE DIRECT CONTROL OF A TRAINED OPERATOR LASER RADIATION LEVELS WILL NOT EXCEED THE LIMITS OF CLASS II AT ANY POINT LESS THAN 3 METERS ABOVE ANY SURFACE UPON WHICH A PERSON IN THE AUDIENCE IS PERMITTED TO STAND OR 2.5 METERS IN LATERAL SEPARATION FROM OR BELOW ANY POSITION WHERE A PERSON IN THE AUDIENCE IS PERMITTED TO BE UNLESS PHYSICAL BARRIERS RESTRICT ACCESS BY THE AUDIENCE TO SUCH LEVELS. THE OPERATOR WILL MAINTAIN CONSTANT SURVEILLANCE OF THE LASER DISPLAY AND IMMEDIATELY TERMINATE EMISSION OF LASER RADIATION IN THE EVENT OF EQUIPMENT MALFUNCTION, AUDIENCE UNRULINESS OR OTHER UNSAFE CONDITIONS.
- g. THE MAXIMUM LEVELS OF LASER RADIATION (*output power*) WILL NOT EXCEED THOSE REQUIRED TO PERFORM THE INTENDED FUNCTION OF THE PRODUCT.
- h. WRITTEN SET-UP, ALIGNMENT AND TEST PROCEDURES WILL BE PROVIDED TO AND FOLLOWED BY THE OPERATOR OR OTHER RESPONSIBLE PERSON PRIOR TO USE OF THE LASER LIGHT SHOW AT EACH LOCATION. THESE STEP-BY-STEP PROCEDURES WILL BE DESIGNED SO THAT WHEN FOLLOWED, THE LASER LIGHT SHOW WILL COMPLY WITH THE CONDITIONS OF THE APPROVED VARIANCE. THE RESULTS OF THE REQUIRED TEST AND CHECKS WILL BE RECORDED AND A COPY RETAINED WITH THE LIGHT SHOW BY THE OPERATOR OR OTHER RESPONSIBLE PERSON. THE RECORD WILL INCLUDE (1) SKETCHES SHOWING THE LOCATION OF THE LASER PROJECTOR(S), OPERATOR(S), PERFORMER(S), AUDIENCE, BEAM PATHS, VIEWING SCREENS, WALLS, MIRROR BALLS, AND OTHER SURFACES THAT MAY BE STRUCK BY THE LASER BEAM; (2) INFORMATION ON SCANNING PATTERNS, VELOCITY AND FREQUENCY; AND (3) LASER RADIATION LEVELS.
- i. SET-UP, ALIGNMENT, CHECKOUT AND TESTING SHALL BE PERFORMED USING THE MINIMUM LASER RADIATION LEVELS NECESSARY.
- j. PROCEDURES WILL BE ESTABLISHED AND FOLLOWED FOR THE WRITTEN NOTIFICATION OF APPROPRIATE FEDERAL, STATE, AND LOCAL AGENCIES OF THE ITINERARIES, OR ANY OTHER REQUIRED INFORMATION. SPECIFICALLY, THE FEDERAL AVIATION ADMINISTRATION (FAA) WILL BE NOTIFIED IN ADVANCE OF SHOWS USING PROJECTIONS INTO THE SKY. STATE AND LOCAL RADIATION CONTROL OFFICES WILL BE NOTIFIED IN ADVANCE OF ALL SHOWS WITHIN THEIR RESPECTIVE JURISDICTIONS. (*Lists of Federal and State offices are available from the Bureau of Radiological Health upon request.*)

14 THE BUREAU OF RADIOLOGICAL HEALTH WILL BE NOTIFIED OF THE INTENDED PLACE AND DATE OF ASSEMBLY (tour itinerary) OF EACH LASER LIGHT SHOW TO BE GIVEN UNDER THE APPROVED VARIANCE AS SOON AS THE PLACE AND DATE CAN BE DETERMINED BY THE APPLICANT. IN ADDITION, A DESCRIPTION OF EACH SHOW AND A LISTING OF ALL EFFECTS TO BE UTILIZED IN EACH LOCATION, IN SUFFICIENT DETAIL TO CONFIRM COMPLIANCE WITH THE CONDITIONS OF THE VARIANCE, WILL BE PROVIDED TO THE BUREAU OF RADIOLOGICAL HEALTH. THIS NOTIFICATION WILL BE SENT TO THE DIRECTOR, DIVISION OF COMPLIANCE, HFX-400, BUREAU OF RADIOLOGICAL HEALTH, 5600 FISHERS LANE, ROCKVILLE, MARYLAND 20857.

15. REMARKS

The laser lighting effects for this show are produced by one model TL-24 D laser projection system manufactured by Precision Projection Systems Incorporated located at 10755 Artesia Blvd. #M, Artesia, CA 90701. Serial # 242

This system has been certified by Precision Projection Systems to be in compliance with the performance standards for laser productions except for certain characteristics as authorized by variance # 83V-0151 effective June 6, 1986.

Further information on this system and the operator is available in the form of a Laser Product Report and any various supplementary reports filed with the CDRH under accession number to be issued by the CDRH.

A report on a laser light show which describes in detail the laser effects used in this production has been submitted to the CDRH. The accession number for this submission will be available upon issuance by the CDRH.

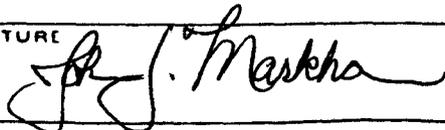
Performances will be conducted with the employees of Chameleon Productions acting as system operators.

Chameleon Productions projectors will utilize LM scanning software and hardware; therefore, the radiation levels will be the same. Please refer to LM's file on calculations for scanned laser radiation by Seigi Inatsugu, PhD. These calculations will be the same as to the reference to LM and LMS projectors.

CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading or incorrect in any material way. I have submitted/will submit all reports required by 21 CFR 1002.10 and 1002.12 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Bureau of Radiological Health to supply such other information that may be necessary to evaluate and act on this application.

16. SIGNATURE



17. TITLE

General Partner

Postmark DEC 3, 1987 73

FOOD AND DRUG ADMINISTRATION
ATTENTION: HEARING CLERK RM 4-65
5600 FISHERS LANE
ROCKVILLE, MD 20857

FIRST CLASS