

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. 0910-0025 Expiration Date: October 31, 2000 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.		3. Mail your application to the FDA Dockets Management Branch, Room 1065, 5630 Fishers Lane, Rockville, MD 20852.		
2. Submit an original and four (4) copies.		4. Enter Docket Number if assigned.		
1. NAME OF COMPANY - Vanderbilt Museum and Planetarium				
2. ADDRESS OF COMPANY (Include ZIP Code) 180 Little Neck Road, Centerport, NY 11721				
3. NAME OF RESPONSIBLE PERSON Dave Bush		4. TELEPHONE NO (Include area code) 631-854-5546		5. DATE OF SUBMISSION October 15, 2003
6. This applicant requests the variance to be in effect for a period of <u>2</u> years from the date of issue and requests to <u>renew</u> <u>1</u> times 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) LFI International - Rainbow e3505 Projector with Coherent Star laser				
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)		c. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION <input checked="" type="checkbox"/> MORE THAN 15 DAYS <input type="checkbox"/> MORE THAN 5 BUT NOT MORE THAN 15 DAYS <input type="checkbox"/> LESS THAN 5 DAYS		
c. PRODUCT IS INTENDED FOR USE IN A <input checked="" type="checkbox"/> PLANETARIUM OR OTHER DOME PROJECTION STRUCTURE <input type="checkbox"/> THEATER <input type="checkbox"/> DISCOTHEQUE OR NIGHT CLUB <input type="checkbox"/> PAVILION <input type="checkbox"/> INDOOR ARENA <input type="checkbox"/> OUTDOOR ARENA <input type="checkbox"/> MUSEUM <input type="checkbox"/> OUTDOOR ENCLOSE AREA <input type="checkbox"/> OTHER (Specify)		f. TOUR IS INTENDED TO RUN FOR <input type="checkbox"/> MORE THAN 6 MONTHS <input type="checkbox"/> 1-6 MONTHS <input type="checkbox"/> LESS THAN 1 MONTH <input checked="" type="checkbox"/> NOT APPLICABLE (has a tour) <input type="checkbox"/> OTHER (Specify)		
d. PRODUCT IS INTENDED TO BE USED <input checked="" type="checkbox"/> AT ONLY ONE (fixed) LOCATION <input type="checkbox"/> AT A VARIETY OF (roving) LOCATIONS <input type="checkbox"/> OTHER (Specify)		e. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS <input checked="" type="checkbox"/> FRONT SCREEN PROJECTIONS <input type="checkbox"/> REAR SCREEN PROJECTIONS <input 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 type="checkbox"/> STATIONARY IRRADIATION OF ROTATING MIRROR BALL(S) OR OTHER MIRRORED SHAPES <input 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)		
8. LASER RADIATION LEVELS				
LASER MEDIUM (Ar, He-Ne, etc)		WAVELENGTHS (nm)		PEAK POWER (Watts)
Argon & Krypton		457.9 - 647.1		3.5 W
9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE Laser system scans CW at 0-30,000 pps, with an amplitude of -90 degrees optical.				
10. REASON FOR REQUESTING VARIANCE <input 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 checked="" type="checkbox"/> OTHER OR ADDITIONAL EXPLANATION (Specify). This is a new system that has been purchased by the Vanderbilt Planetarium				

FORM FDA 3147 (10/79)

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

(X) 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

(X) 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. (X) ALL LASER PRODUCTS, SYSTEMS AND PROJECTORS WILL COMPLY WITH 21 CFR 1040.10 FOR LASER PRODUCTS OF THEIR CLASS (Specify class(es)) IV

b. (X) 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. (X) 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 OR RADIATION SHALL NOT BE PERMITTED.

d. (X) SCANNING SERVICES, 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. (X) WHEN LASER LIGHT SHOW 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. (X) 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. (X) THE MAXIMUM LEVELS OF LASER RADIATION (output power) WILL NOT EXCEED THOSE REQUIRED TO PERFORM THE INTENDED FUNCTION OF THE PRODUCT

d. (X) WRITTEN SET-UP, ALIGNMENT AND TEST PROCEDURES WILL BE PROVIDED TO AND FOLLOWED BY THE OPERATOR OR OTHER RESPONSIBLE PERSON PRIOR TO USE OF A 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 BEAMS, (2) INFORMATION ON SCANNING PATTERNS, VELOCITY AND FREQUENCY, AND (3) LASER RADIATION LEVELS

i. (X) SET-UP, ALIGNMENT, CHECKOUT AND TESTING SHALL BE PERFORMED USING THE MINIMUM LASER RADIATION LEVELS NECESSARY

j. (X) 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. (List of Federal and State offices are available from the Bureau of Radiological Health upon request.)

14. (X) THE BUREAU OF RADIOLOGICAL HEALTH WILL BE NOTIFIED OF THE INTENDED PLACE AND DATE OF ASSEMBLY (to-
 (factory) 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

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

David Bull

17 TITLE

Technical - Production Coordinator

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October 23, 2003

FDA Dockets Management Branch
HFA-305, Room 1065
5630 Fishers Lane
Rockville, MD 20852

RE RUSH request for processing - the variance application was faxed on 10/23/03

To whom it may concern,

Vanderbilt Museum and Planetarium located at 180 Little Neck Road, Centerport, NY 11721, will begin operating laser shows starting on December 5, 2003. LFI will be installing the equipment and conducting setup from December 1-4, 2003 and wishes to turn over the operation to Vanderbilt Museum and let them operate under their own variance. The Vanderbilt Museum and Planetarium is planning on running these shows year round. Please find attached a signed copy of the variance application and a full laser show report. If you have any questions or concerns please don't hesitate to contact me. We would greatly appreciate any efforts made by you and your staff to process this by the time shows start on December 5, 2003.

Sincerely,



Roberta McHatten
Director/LSO
Production & Technical Services

attachments: Laser Light Show Report
Variance request form (Included in Light Show Report)

cc. Manuel Karos, CDRH