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| DEPARTMENT OF HEALTH AND HUMAN SERVICES 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, 2013 See Page 4 for OMB Statement. <hr/> DOCKET NUMBER |
| NOTE: No laser light show, projection system, or 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 Division of Dockets Management (HFA-305), Food and Drug Administration, Rm 1061, 5630 Fishers Lane, Rockville, MD 20852. 4. Enter docket number if assigned. | | |
| 1. NAME OF COMPANY _____ | | |
| 2. ADDRESS OF COMPANY <i>(Include ZIP Code)(If P.O. Box is used, include actual street address also.)</i> _____ | | |
| 3. NAME AND TITLE OF RESPONSIBLE PERSON _____ | 4. TELEPHONE NO. <i>(Include area code)</i> _____ | 5. DATE OF SUBMISSION _____ |
| 6. THE APPLICANT REQUESTS THE VARIANCE TO BE IN EFFECT FOR A PERIOD OF _____ YEARS FROM THE DATE OF ISSUE. <i>(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.)</i> | | |
| 7. PRODUCT DESCRIPTION AND USE | | |
| a. LIST NAME AND/OR MODEL NUMBER(S) FOR THE LASER LIGHT SHOW(S) AND PROJECTOR(S) _____ | | |
| 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 type="checkbox"/> A laser light show <input type="checkbox"/> Other <i>(Specify)</i> _____ | f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION <input 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. <input type="checkbox"/> PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS | g. TOUR IS INTENDED TO RUN FOR <input type="checkbox"/> More than 6 months <input type="checkbox"/> 1 - 6 months <input type="checkbox"/> Less than one month <input type="checkbox"/> Not applicable <i>(Not a tour)</i> <input type="checkbox"/> Other <i>(Specify)</i> _____ | |
| d. PRODUCT IS INTENDED FOR USE IN A <input type="checkbox"/> Planetarium or other dome projection structure <input type="checkbox"/> Theater <input type="checkbox"/> Hotel/motel ballroom or meeting room <input type="checkbox"/> Store displays <input type="checkbox"/> Trade show or convention <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 unenclosed area <input type="checkbox"/> Other <i>(Specify)</i> _____ | h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS <input type="checkbox"/> Front screen projections <input type="checkbox"/> Rear screen projections <input type="checkbox"/> Holographic displays <input type="checkbox"/> Multiple reflection/diffraction effects <input type="checkbox"/> Audience scanning <i>(Also includes scanning any accessible uncontrolled areas)</i> <input type="checkbox"/> Reflections from stationary mirrors or mirrored surfaces <i>(Beam Matrices)</i> <input type="checkbox"/> Stationary irradiation of rotating mirror balls, etc. <input type="checkbox"/> Scanning irradiation of rotating mirror balls, etc. <input type="checkbox"/> Fiber optic projections <input type="checkbox"/> Fog, smoke, or other scattering enhancement effects <input type="checkbox"/> Other <i>(Specify)</i> _____ | |
| e. PRODUCT IS INTENDED TO BE USED <input type="checkbox"/> At only one <i>(Fixed)</i> location <input type="checkbox"/> At a variety of <i>(Tour)</i> locations <input type="checkbox"/> Other <i>(Specify)</i> _____ | | |
| 8. LASER RADIATION LEVELS | | |
| LASER MEDIUM <i>(Ar, He-Ne, etc.)</i> | WAVE LENGTHS <i>(nm)</i> | PEAK POWER <i>(watts)</i> |
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| 9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE _____ | | |
| 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 type="checkbox"/> Other or additional explanation <i>(Specify)</i> _____ | | |