CDRH Variance Package: Cover Sheet

Variance applicant contact information:

Contact Name: Jeff Vyduna
Company Name: Big Arts Organizati
Address: 2320 Cecilia Ave
San Francisco, CA 94116

Email: jeff@bigbigbig.org
Phone: +1 773 895-5995

Submitter contact information (if different than variance applicant):

Contact Name: _____
Company Name: _____
Address: _____

_____

_____

Email: _____
Phone: _____

The package includes the documents indicated below:

- [✔] Submission checklist (this document, no additional cover letter needed)
- [ ] Product type:
  - [ ] Laser Light Show
  - [ ] Other
- [✔] Variance request type:
  - [ ] original [✔] renewal [ ] amendment
  - Variance Number (*yyyy*-V-*xxxx*): 2022-V-0450
- [✔] Laser Light Show Report (Form FDA 3640) or Report Supplement
- [✔] Other document(s)*
  - Specify: 3636 FDA Annual Report (for 2024)

**Note to current LLS variance holders:* Please submit the annual report (Form FDA 3636) by September 1st each year to have your variance approval automatically extended another year. Clarification of laser light show procedures and the automatic renewal policy can be found in Laser Notices #51 and 55. See: https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/laser-light-shows. Do not use this cover sheet for submitting annual reports, unless your variance has expired (e.g. you failed to submit a previous annual report) and you need to request a variance renewal.

CDRH Variance Application: Checklist

In order to apply for a variance to request approval of a different way to provide the same safety that the FDA mandatory performance standard requirements require, you need to submit a variance request to CDRH and await an approval letter. The checklist below should help you confirm completeness of your variance application.

In the specific case where you apply for a variance for a Class IIIB/3B, Class IV/4, or Risk Group 3 laser light show (LLS), laser projector, laser-illuminated projector (LIP), laser-illuminated lighting instrument (LILI), or other demonstration laser product (21 CFR 1040.10(b)(13)), please use and include this checklist in your variance application package to ensure your application is processed as quickly as possible. Please refer to Appendix A, below, for the documents that should be included in your variance application package.

Variance Application Checklist

- ☑ All applicable sections of all required forms/documents are completed
- ☑ The variance applicant's (manufacturer's) email address is provided on all forms.
- ☑ All forms are signed by the manufacturer
- ☑ All forms include at least one make and model of laser product in the applicable section.
- ☑ If submitter is different than the manufacturer, the submitter contact information and email are included
- ☑ If requesting renewal or amendment of a previous or current variance, include the Variance Number of the variance to be renewed/amended.
- ☑ Email all documents as separate PDF attachments, including this cover sheet/checklist, to the Center for Devices and Radiological Health (CDRH):

  RadHealthCustomerService@fda.hhs.gov

  - ☑ Email subject line includes the applicant's firm name
  - ☑ Variance application/renewal/amendment filename includes the applicant's firm name and date

CDRH/DCC will process your variance application package and issue acknowledgement letters with Accession numbers for each variance application and report. Variance applications are forwarded to the FDA Dockets Management Staff (DMS), who will also issue you an acknowledgement letter with your Docket number. Variance applications do not need to be separately sent to DMS.

Appendix A: Documents to include in your variance application package

Product Type Entity Type	Variance Application (Form 3147)	Show Report (Form 3640)	Laser Product Report (Form 3632)	Other
Light Show Producer (considered a manufacturer)*	**X**	**X**		
Laser Projector Manufacturer	**X**	**X**	**X**	
Laser Projector Dealer/Distributor	**X**	**X**		
LIP/LILI Manufacturer	**X**		**X**	
LIP/LILI Dealer/Distributor	**X**			
LILI User (installed within the hazard distance)	**X**			
LILI User (installed beyond hazard distance)**	***(no variance needed if installed beyond the hazard distance and according to manufacturer's installation instructions by a manufacturer-authorized installer)***			
LIP User (temporary installation)	**X**	**X**		
LIP*** User (permanent installation)	***(no variance needed if installed according to manufacturer's installation instructions by manufacturer-authorized installer)***			
Variance Renewal		Only if previously submitted report needs to be updated		This cover letter, missing annual reports
Variance Amendment		Only if previously submitted report needs to be updated	Only if previously submitted report needs to be updated	This cover letter including requested amendments

*The act of assembly of a laser light show using a previously manufactured laser or laser product results in the creation or manufacture of a "new" product. The creation of this new product may involve the addition of such components as display screens, mirrors, smoke/fog and optics but may result from merely changing the intent and use of the original laser. Hence, the person who produces the "new" product is considered a "manufacturer" if such person is engaged in the business of manufacturing laser light shows. This policy, including additional details, can be found in Laser Notice #22, published on November 22, 1977.

** LILI users do not require a variance if all LILIs are installed by a manufacturer-authorized installer in locations where the distance between the LILI's aperture and any accessible location is greater than the Hazard Distance specific to that LILI. LILI's installed within the Hazard Distance that use engineering controls or other mechanisms to prevent exposures that exceed the lmits of RG2 do not require a variance if installed by a manufacturer-authorized installer and if the configuration of the exposure controls are not user-accessible. This policy applies to LILIs given the similarity of their intended use and radiation hazard to LIPs.

*** Laser Notice 57, Section IV – Policy part (d)(v)