9125 Whiskey Bottom Rd, Suite A
Laurel, MD 20723-1333
(P) 301-543-1981
(F) 877-230-6328
www.x-laser.com

# Your Guide to the FDA Annual Report

One of our main objectives as a laser company is to make sure that our clients know the importance of laser safety and legal compliance. Regarding the legal side, we want to make sure the compliance aspects of owning and using a high-powered laser system remain approachable and easy, so that you can keep producing legal and impactful laser shows. While many aspects of filing documents with the U.S. government can be intimidating, we have taken every effort to simplify and streamline these processes for laserists, for users of our EZ Variance system and for laser light show variance holders in general.

As part of the effort to make sure that our clients can maintain compliance in a way that is simple and quick, we've put together this guide to assist with filing your annual report with the FDA. The annual report is a simple submission, **due by September 1**, that tells the FDA you're still using your variance, and it is what allows your variance to renew. With the information provided here, you should be able to complete and submit your FDA annual report in **less than 30 minutes**. There are only a few fields to complete so it should not take long, and there is **no charge to file your annual report.**

This guide contains an FAQ and step-by-step instructions to guide you when filling out the annual report form that we've created specifically for X-Laser users. For your reference, we also have a sample of an annual report available. Furthermore, if you use lasers made by another brand or would like to use FDA Form 3636 from scratch instead, we have that form available too. You can download all of the material related to the FDA annual report by visiting [www.x-laser.com/annualreport](www.x-laser.com/annualreport).

Once you complete the annual report process the first time, it should be very easy each year thereafter. Even for X-Laser, as a laser hardware manufacturer with much more data to provide to the FDA, our annual report only takes us about an hour to complete each year.

**Before you begin, please note the following:**

**1)** Please **do not send anything to X-Laser**, electronically or otherwise. We cannot process annual reports. Completed annual reports should be **printed, signed and sent** via USPS, UPS or FedEx to:

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER – WO66-G609
ATTN: ELECTRONIC PRODUCT REPORTS
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

**2)** You can send your annual report using standard postage, but sending your annual report via certified mail with a **tracking number is preferred**.

**3)** If you use high-powered laser in any way and have never filed an annual report as part of maintaining your laser light show variance, that's not great, but it's better to file now than never. Please go ahead and file your annual report. Staff from the FDA will be in touch if they have any concerns. **If you do not use high-powered lasers, you do not need to do anything.**

Again, **we are here to help**! Please contact us at **variances@x-laser.com** if you have any questions.

Brightly,
The team at X-Laser USA

X-LASER® LASER WITHOUT LIMITS

# FAQ: ANNUAL REPORT

## What is an annual report and why do I need to file one?

An annual report is a document produced by you, the user of an X-Laser product, to the U.S. FDA regarding your use of high-powered lasers. The annual report is required to maintain your laser light show variance because it informs the FDA that you are still actively using your variance.

## If I do not file my annual report, what will happen?

If you do not file an annual report, the FDA assumes that you are no longer using your variance, and as a result, the FDA will allow your variance to expire. If you file you annual report, the FDA will renew your variance automatically.

## Why are there two versions of the annual report form?

We have prepared a version of the annual report that is pre-filled with some data that covers many of the questions that the FDA asks as part of the annual report. This file is ready for you to input your contact information, some data about the X-Laser system(s) you use, and your signature. The version of the annual report with the pre-filled data is applicable for the vast majority of X-Laser users. In case the answers in the pre-filled X-Laser form are not applicable to how you use your laser system, or if you use lasers made by a different company, your other option is to use FDA Form 3636. Regardless of which version of the annual report form you use, the report you file with the FDA must be truthful and an accurate representation of how you use high-powered laser. We **strongly recommend** not altering the forms in any way other than to input your answers. You **do not** need to file both versions of the form, only whichever you choose to use.

## The form says "manufacturer" but I am a laser user, not a manufacturer. What do I do?

The FDA uses an unusual definition of the word "manufacturer" that includes companies like X-Laser who actually make the laser hardware and the users of those laser products. You, as a user of a high-powered laser system, "manufacture" a laser light show. If it helps, you can replace the word "manufacturer" with "producer" in your mind as you complete the form. No matter what, please remember to **not make any changes** to the actual form or its questions.

## When is the form due?

Your annual report is due at the **end of August** of each year, which covers the previous "laser show year" beginning July 1 and ending June 30.

X-LASER
LASER WITHOUT LIMITS

# INSTRUCTIONS

## *How to complete your FDA Annual Report for Laser Light Show systems*

**First and foremost,** please use only the pre-filled version of the annual report form if it accurately represents your laser light show usage. For example, if you received a complaint letter regarding improper laser safety procedures, you'll have to use the blank version of the annual report form to be able to accurately complete Part 6 on page 5.

## Page 1

- "Name" should be the name of your company or your name if there is no company involved. This field tells the FDA who registered the variance holder is, whether that is a company or an individual.
- "Address" should be your business address.
- The phone number you provide should be the best possible phone number used to reach you.
- The date to input is today's date.

## Page 2

- The report date (1A) is today's date.
- "Company name" (1B) should be the same as the "Name" field from page 1, regardless of whether you are a company or not.
- "Address" (1C) should be your business address.
- "Position" (1D) should be your role within your company. If you do not have a designated role, you can just use your name.
- For section 1F, the dates should reflect the previous "laser show year" as noted by the FDA to be July 1 through June 30. For example, if you're filing your annual report and today's date is in 2019, the first blank in section 1F will be 2018 and the second blank will be 2019.
- For Part 2, please remember that your laser light **show** is considered a "product" and you are considered a "manufacturer." As long as you are still in business and using your lasers, please leave the "X" in the top option selected as is.

# INSTRUCTIONS (CONT.)

## *How to complete your FDA Annual Report for Laser Light Show systems*

### Page 3

- Your "Accession Number" (3.1A) is your variance number, docket number or accession number provided by the FDA. When your variance application was originally filed, you should have received at least one letter from the FDA, which will prominently display one or more of these numbers. These numbers tell the FDA that you have previously filed a variance application. If you do not have an accession/docket/variance number, you can write "Pending" or "Variance Approval Pending," but one of the aforementioned numbers is highly preferable. You can also find your accession/docket/variance number by contacting the Dockets Management at the FDA, and they will be able to look up your application.

- For "Model Numbers" (3.1C), enter the model name(s) of the X-Laser product(s) you are using. For example, if you own a Mobile Beat Mirage, just write that. If you also use high-powered laser products not made by X-Laser, you need to report them in a separate attachment with your annual report and write "See Attached" in box 3.1C. For such products, you need to include model numbers/names, where the products were manufactured and by whom, etc. Contact the other manufacturer(s) to obtain their FDA reporting details.

- For "Permanent or Touring" (3.2C), the form simply asks if the lasers remain in one venue permanently, or if they travel and are used at multiple venues. Write whichever is accurate for the laser system you use, and an answer of "both" is OK too.

- For "Number of Shows Performed" (3.2F), write in the number of times that you used your laser in the past "laser show year" i.e. July 1 through June 30. An approximate number is acceptable here.

# INSTRUCTIONS (CONT.)

## How to complete your FDA Annual Report for Laser Light Show systems

### Page 4

- For "Model Number or Name of Show" (5A), write whatever your laser show is called. If you don't have a specific name for your laser show, it's OK to make up one. For example, if your nightclub is called "Poker," you could input "Poker's Laser Show" into section 5A of the annual report.
- For "Number Produced" this is the same as section 3.2F, and you simply write the same number from section 3.2F, an approximate total of how many times you used your laser in the past "laser show year."

No other sections of the annual report form require your input unless your answers to the pre-filled portions of the form (Part 4, for example) are different or not applicable to how you use your laser(s). In this case, you would need to complete the blank annual report form and supplement your annual report with the appropriate data.

That's it! When you are finished, review your answers throughout, print the document, sign your name in section 1E and mail your annual report to:

U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER - W066-G609
10903 NEW HAMPSHIRE AVENUE
SILVER SPRING, MD 20993-0002

***REMEMBER TO SIGN BOX 1E BEFORE MAILING!***

If you would like more information about the FDA annual report or wish to have more guidance with filling out a blank copy, see https://www.fda.gov/media/72606/download for the complete guide, which is also accessible by searching the internet for "FDA form 3636" or using the keywords "FDA annual report laser guide."