X-LASER USA
PO BOX 353
LAUREL, MD 20725

FDA ANNUAL REPORT FAQ

Instructions follow on page 2.

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

An annual report is a report made by you, the user of an X-Laser product, to the FDA concerning your use of high powered lasers. The annual report is required to maintain your variance because it lets the FDA know that you are still using your variance.

If I do not file it, what will happen?

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

Why are there two annual report files?

We have created one file pre-filled ready for your contact information, a few pieces of data, and your signature. This file is already mostly completed with common answers to FDA questions. The other file is a blank annual report form in case one or more of the answers in the pre-filled version are inappropriate or not applicable to your situation. You are welcome to use either version but in any case the filed report must be a truthful and accurate representation of your laser business. You DO NOT need to file both, only one.

The blank form is an unlocked PDF which can be copied into a word document for your convenience. WE STRONGLY recommend NOT changing the form in any way other than to fill in answers. We also recommend using the same answers from the locked form wherever appropriate.

The form keeps saying “manufacturer” but I am a user, not a manufacturer.

The FDA uses an unusual definition of the word “manufacturer” that includes companies like X-Laser who actually make laser systems AND all users of those products. You, as a high powered laser user, “manufacture” a laser light SHOW. If it helps, you can replace the word manufacturer with “producer” or some other variation in your mind as you read the form. Just please do not change the actual form.

When is the form due?

Typically the forms are due in August of each year for the “laser show year” beginning July 1 and ending June 30.

INSTRUCTIONS FOR COMPLETION:

FIRST AND FOREMOST, please only use the pre-filled version of this form if it accurately represents your laser light show usage. If for example, you received a customer complaint letter regarding improper safety procedures, you will need to use the blank version of this form to accurately complete Part 6 on page 5.

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Name should be your company name or your name if there is no company involved. This field should be the same as the variance holder. Address should be your business address if you are a business or a home address is also acceptable if there is not a business involved. The phone number is a good contact number for you and the date is today's date.

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Report date is today's date, "Company Name" should be the same as the first page regardless of whether you are a company or not, address should be the same as page 1.

You do not need to report a "position" in 1D if it is not applicable, your name will be fine and then please print out the form and sign in 1E when complete. For 1F the first blank should be LAST YEAR's year and the second blank should be THIS YEAR's year.

For part 2 please remember that your laser light show is considered a "product" and you are a "manufacturer." As long as you are still in business and using your lasers, please leave the X in the top space as currently written.

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Your "accession number" is your variance number, docket number, or accession number. When your variance application was filed you should have received at least one letter which will prominently display one more more of these numbers. This tells the FDA that you have filed a variance application. If you do not have the number, you may also write in "Pending" or "Variance Approval Pending" but a number is highly preferable. You may also call Docket's Management at the FDA (contact information changes all the time, refer to fda.gov) and they will be able to look up your application.

In 3.1C enter the model numbers of X-Laser product you are using. You ONLY need to enter the model numbers. Products not made by X-Laser should also be reported here as a separate attachment in which case you would write in "See Attached" and then attach a separate page listing the products you are using, their model numbers, where they were made, etc. Contact the other manufacturer for their reporting requirements.

3.2c is asking if the lasers are in a permanent install or they are used at mobile events. Either answer or "both" is fine.

3.2f. Write in the number of times you used your laser in the past year. An approximate number is acceptable. This is also used for 5b below.

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5a. What is your show called? Make something up if you like but a club called “Poker” would have a show called “Poker’s Laser Show.” You could also call it “Lasers Adagio,” “Light Up The Night,” or whatever else you may want. 5b then is the same answer as 3.2f above.

No other sections require your input unless a section is incorrect in which case you will need to complete the blank form.

PLEASE MAIL YOUR COMPLETED AND SIGNED FORM TO:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

DO NOT FORGET TO SIGN IN BOX 1E BEFORE SENDING THE REPORT.

If you would like more information about the annual report or wish to have more guidance for filling out a blank copy, please visit http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081603.pdf to download the complete guide and note that you only need to complete section 4 as that is the only section which pertains to laser light shows. If that link ever changes, please visit www.fda.gov and use the search box in the upper right to search for FORM FDA 3636 or keywords: annual report laser guide.