Comment submitted by Patrick Murphy on FDA's May 5 2014 Draft Guidance

My name is Patrick Murphy; I am writing on behalf of myself as a private citizen, and not as a representative of any group or association. A brief background of my decades-long history of working with laser safety, and especially to reduce aircraft illumination events, is in the Appendix after the end of this document.

This comment is in response to FDA's May 5 2014 Draft Guidance proposal, which attempts to define certain types of lasers as "surveying, leveling or alignment" (SLA) lasers. The guidance would give FDA specific authority over these laser types.

SCOPE OF THE COMMENTS

In these comments, I am primarily concerned with the section of FDA's proposal defining "laser pointers" as SLA lasers. I am not an expert on the other laser types that FDA proposes to regulate as SLAs (levels, tools incorporating laser guides, gun sights, target designators, night vision illuminators, or visual disruptors).

I assume that by "laser pointers" FDA means, broadly, battery-powered handheld lasers both under 5 mW -- traditionally regulated as "pointers" -- and also those over 5 mW, which I will call "handhelds" and which often look and operate like under-5mW pointers.

My comments are restricted to laser pointers and handheld lasers as they relate to surveying, leveling or alignment lasers. The possible use of these lasers for demonstration or medical purposes will not be discussed herein.

Finally, my analysis of pointers and handhelds assumes a product that is FDA compliant because it is properly labeled, it has all the safety features required for its Class, and the manufacturer has met their reporting requirements to FDA. I am well aware that many pointers and handhelds may be mislabeled, may not have all safety features, and some may be illegally imported with false or missing documentation. Such lasers already are subject to FDA regulatory authority until they come into compliance, and thus will not be discussed further.

SUMMARY AND OVERVIEW

This comment will make the following points in some detail:

1) In the existing regulation, 21 CFR 1040.10 and 1040.11, FDA has no direct authority over laser pointers, compact lasers, battery-powered lasers, ergonomic handheld lasers, or lasers used in open spaces or unrestricted environments. None of these terms or concepts are found in the wording of 21 CFR 1040.10 and 1040.11.

> 1A) The May 5 2014 Draft Guidance is stretching the English language and logic to try to claim SLA lasers have these features, and that therefore lasers with these features are SLA lasers.

2) FDA is incorrect in a number of key claims about features of SLA lasers:

> 2A) Comparing photos of surveying, leveling and alignment lasers with photos of laser pointers and handhelds shows that these have very different form factors in most cases. Even when an alignment laser may look somewhat similar (cylindrical body), it includes a mount for stable positioning which is almost never a standard feature of a laser manufactured, designed or intended for pointing or general-purpose handheld usage.
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> 2B) FDA has claimed that SLA lasers have certain features. But some of these features are in fact not true or common for SLA lasers. For example, many or most surveying and leveling lasers are not of compact size (e.g., pocketable). Almost all SLA lasers cannot be used handheld since this would not permit accurate measurements.
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> 2C) Other features claimed by FDA are so broad as to apply to almost all lasers. For example, just about any laser could be used in an open space or an unrestricted environment. Similarly, almost all lasers that emit light into open space do so in a straight line -- a laser with curved beams or light is pretty rare.
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> 2D) The FDA also claims that SLA lasers do NOT have certain features. But again, many SLA lasers likely have some of these features: stable power, high quality power supply, remote control actuation.

3) FDA makes a basic logical error in asserting that because some lasers share features with SLA lasers (such as emitting light in a straight line), that therefore lasers with such features are SLA lasers. This is exactly like saying “Medical lasers’ design features include large size, wall-powered, being bulky, and emitting a straight line. Therefore, lasers having these features are evidence that the product was designed for medical use, and they will fall under FDA jurisdiction.” Obviously, this is not valid logic.

4) 21 CFR 1040.10(b)(39) already has a clear definition of surveying, leveling and alignment laser products. This definition is, correctly, based on how a laser is used and

not on what it looks like. Based on this definition, laser pointers and handheld lasers are not used for surveying, leveling or alignment.

> 4A) A comparison of laser pointer usage with the SLA definition shows that pointing at something to call attention to it (e.g. a PowerPoint presentation) does not fall into any of the use cases in 21 CFR 1040.10(b)(39)
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> 4B) More specifically, laser pointers are not "determining ... the position of a point" as set forth in the regulations. A presenter is not interested in determining where exactly a PowerPoint bulleted item is located -- they just want to call other people's attention to the item.
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> 4C) Similarly, a presenter is not interested in defining a straight line between the pointer and the slide. The laser may be dim enough that no straight line is visible (only the end "dot). If a line is visible, the line itself is just a byproduct of light traveling in straight lines; no one in the audience is interested in the line itself.

As a result of the above, there is no regulatory justification for the May 5 2014 Draft Guidance, and this comment recommends that it not be issued. A few other recommendations and suggestions are then provided.

In summary, this comment will show that although FDA may have good intentions in trying to regulate certain types of lasers, they cannot do so with such poorly conceived claims and logically fallacious reasoning -- especially when there is already a clear definition in 21 CFR 1040.10. FDA needs to stick to the definition already in 21 CFR 1040.10 and not "make stuff up."

BACKGROUND

To understand the May 5 2014 Draft Guidance, one first has to have a background of FDA's past regulation of laser pointers.

DEFINITION OF LASER POINTERS

The FDA's regulatory authority over lasers, 21 CFR 1040.10 and 1040.11, does not include laser pointers (e.g., consumer pen-like visible-beam lasers used for directing attention during a presentation). At the time the CFR was drafted, the only laser pointers were relatively bulky and expensive glass-tube or metal-tube gas lasers requiring plug-in-the-wall power. Planetariums might use these for presentations, but not ordinary business people or consumers.

So this is the first important thing to note: ***FDA has no direct authority over laser pointers.*** The word "pointer" is not in 21 CFR 1040.10 or 1040.11. Similarly, **FDA has no direct authority to regulate lasers based on being battery powered, or based on compact size, or based on ergonomic design.**

Any authority which FDA might claim has to come from one of the three classes of laser *uses* which FDA can regulate under 21 CFR 1040.10: SLA, demonstration, and medical laser use. In other words, in order to regulate laser pointers, FDA has to define them as a laser used for demonstrations, surveying, leveling, alignment and/or medical. Obviously the May 5 2014 Draft Guidance proposal attempts to do just this.

When laser pointers began to use diodes, they became battery-powered, smaller, and less expensive. At the end of the 1980s, FDA somehow decided that laser pointers under 5 mW would be regulated by them; I believe the idea was that they fell under the "demonstration laser product" authority in 21 CFR 1040.10.[1]

This led to the current situation: Small, battery-powered, handheld visible-beam lasers are called "laser pointers" by FDA if they are under 5 mW, while lasers above this power are generally known as "handhelds" to distinguish them from the under-5mW pointers.

Previously FDA did not claim that its authority extended to handheld lasers over 5 mW. Such lasers were considered as general-purpose lasers, just like general-purpose lasers that plug in the wall. Handhelds were not subject to FDA regulation as long as they had all safety features required for its laser Class.[2]

The May 5 2014 Draft Guidance proposes to change this. Both "laser pointers" (under 5 mW) and "handhelds" (over 5 mW) would be re-defined as SLA lasers. This would limit any handheld laser (or specifically, any compact, battery-powered, ergonomic handheld, portable laser emitting a straight line) to be under the 5 mW power limit of SLA lasers.

So this is the second important thing to note: **FDA is proposing to widen its authority over any handheld general-purpose laser, including those over 5 mW that currently are not formally regulated by FDA.**

WHY EXTEND REGULATIONS?

In trying to restrict any handheld laser to be below 5 mW, FDA is responding to reports of eye injuries from consumer handhelds. FDA also is responding to the approximately 4,000 reports each year of pilots being distracted or even directly illuminated with laser light. Obviously, the more powerful the laser, the greater the distance at which a person could distract or flash-blind a pilot.[3]

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[1] I have filed two Freedom of Information Act requests but as yet have not received any policy memos, guidance letters, letters to manufacturers, or other documents indicating how FDA came to regulate laser pointers.

[2] At some point in the recent past, FDA began issuing warning letters stating that certain laser products were SLA lasers. I believe handhelds (> 5 mW) were included in this meaning that FDA wanted to restrict them to output below 5 mW. The May 5 2014 Draft Guidance is an attempt to codify this practice.

[3] Fortunately, there is not a linear increase in hazard with power. The hazard distance increases as the square root of the power increase. A 100 mW laser has a hazard range that is 10 times that of a 1 mW laser. A 1 watt (1000 mW) laser's hazard distance is 31 times that of a 1 mW laser.

It is commendable that CDRH, with its limited resources and authority, has come up with a clever way to extend its authority over potentially hazardous laser products. It may well be that handheld lasers have become too powerful for general consumer use, and that some type of regulation, licensing, taxing or other restrictions may be necessary.[4]

Whether or not FDA restrictions on handhelds will have an effect on misuse, I strongly believe that the May 5 2014 Draft Guidance is NOT a valid method for FDA to regulate handheld lasers.

In a nutshell, the FDA is claiming that SLA lasers have certain features — which many do not have — and then in circular logic, is claiming that any lasers with such a feature is therefore an SLA laser. This is like stating that because trucks have an engine, wheels, and steering mechanism, that therefore motorcycles and cars can be regulated as if they are trucks.

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[4] This comment is not the place to discuss in depth whether regulations will work. Some small U.S. beach-town communities have had success with reducing incidents. However, Australia found an opposite effect. After Australia banned laser pointers over 1 mW in 2008, the number of laser/aircraft incidents actually increased. Further, "...the prohibition laws may have detrimentally affected laser pointer safety within Australia without overtly impacting availability....the one thing more hazardous than a correctly labelled high power laser pointer is a high power laser pointer labelled as safe." Quoted from Laser Pointer Prohibition -- Improving Safety or Driving Misclassification" by Trevor Wheatley, School of Engineering and Information Technology, University of New South Wales, Canberra, as published in the Proceedings of the 2013 International Laser Safety Conference.

SPECIFIC OBJECTIONS TO FDA'S PROPOSAL

I set forth three main objections to FDA's proposal:

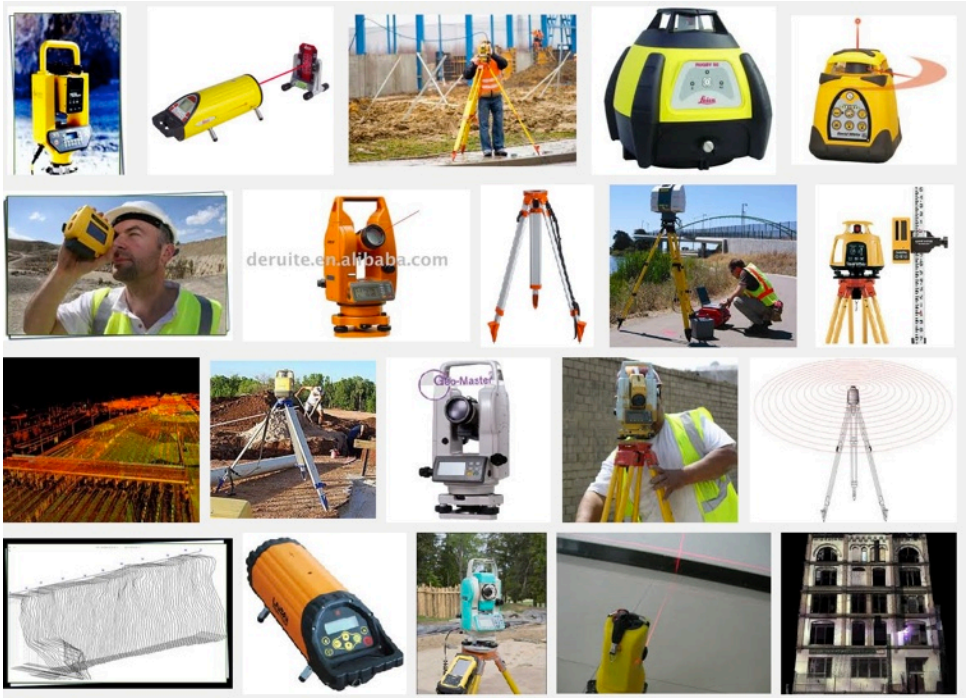
- First, that many or most of the claimed features of SLA laser products are NOT in fact valid, or specific to SLA lasers.
- Second, even if some laser products have certain features of SLA lasers, such as being portable and emitting a straight line, that it is false logic to then turn around and say that any laser product with such features is an SLA laser.
- Third, 21 CFR 1040.10 already has a definition of SLA lasers, correctly based on how the laser is used and not on its "features." This is complete and sufficient justification for FDA regulation of lasers legitimately used for SLA purposes.

SLA LASERS DO NOT LOOK LIKE POINTERS OR HANDHELDS

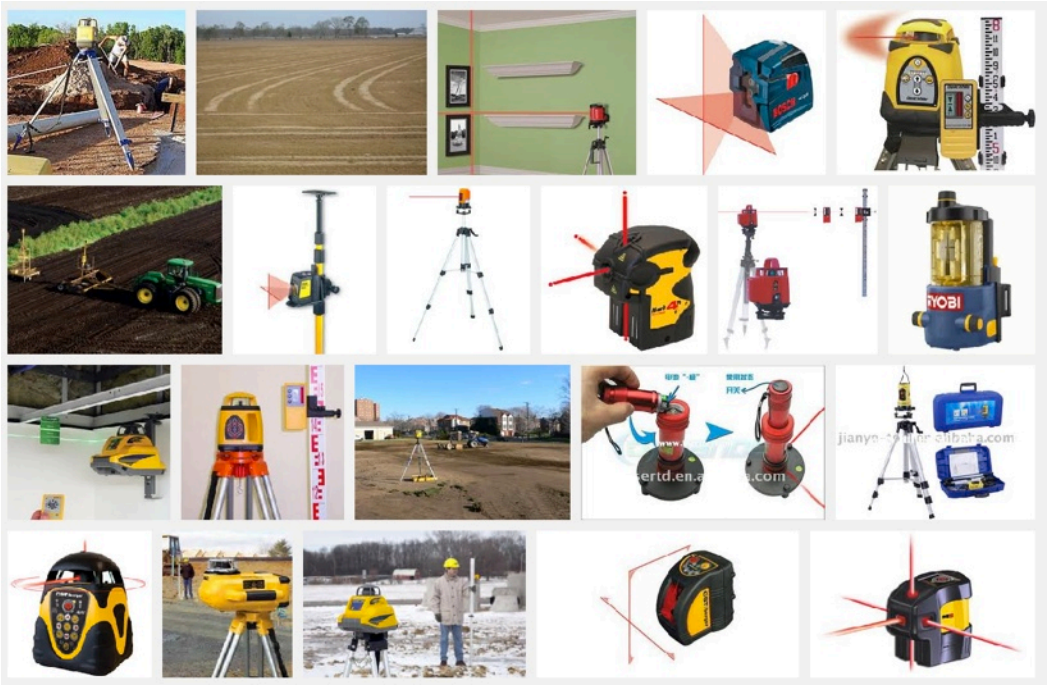
At a very basic level, a laser designed or intended to be held in the hand is the anthesis of a laser being used for something as precise as surveying, leveling or alignment. A SLA laser must have a sturdy, fixed mount so it can be used as a point of reference.

This is shown in photos of actual lasers used for surveying, leveling or alignment. Below are screenshots of Google image searches for these three types of lasers.

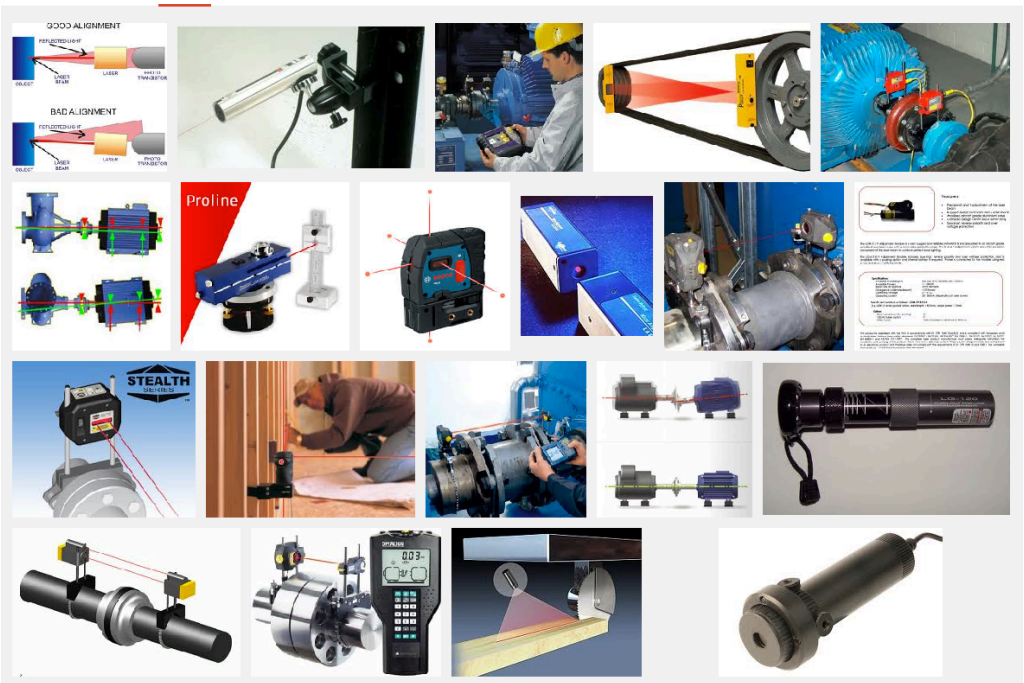
"SURVEYING LASER" GOOGLE IMAGE SEARCH:



“LEVELING LASER” GOOGLE IMAGE SEARCH:

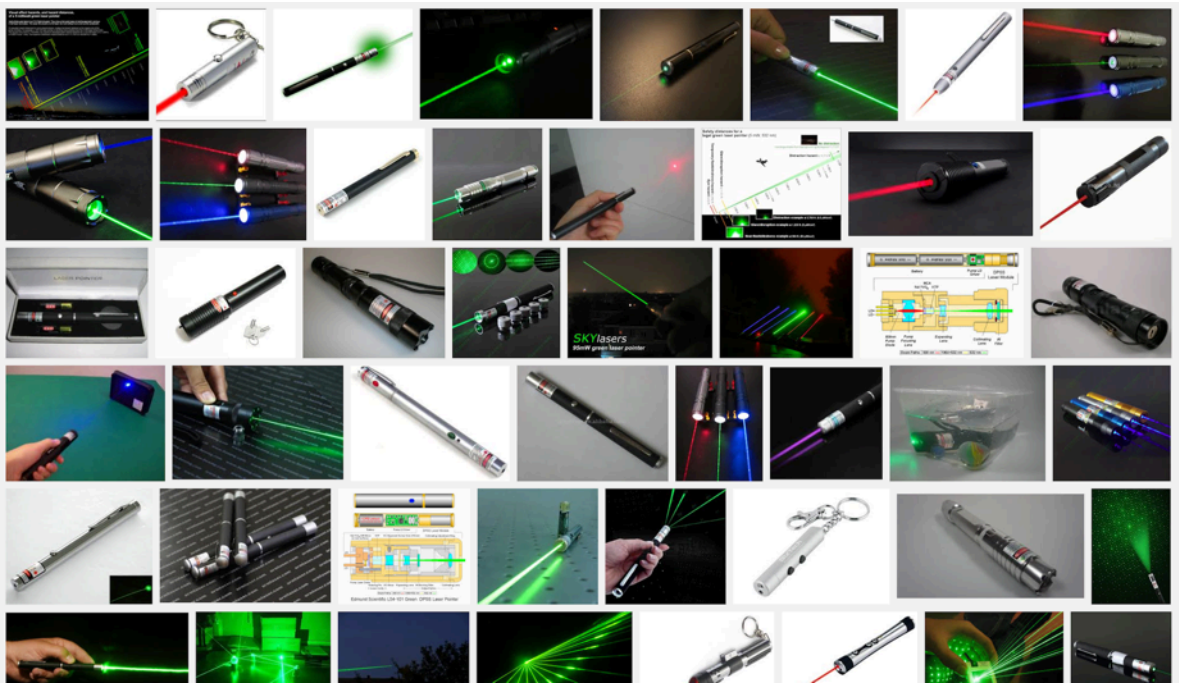


“ALIGNMENT LASER” GOOGLE IMAGE SEARCH:

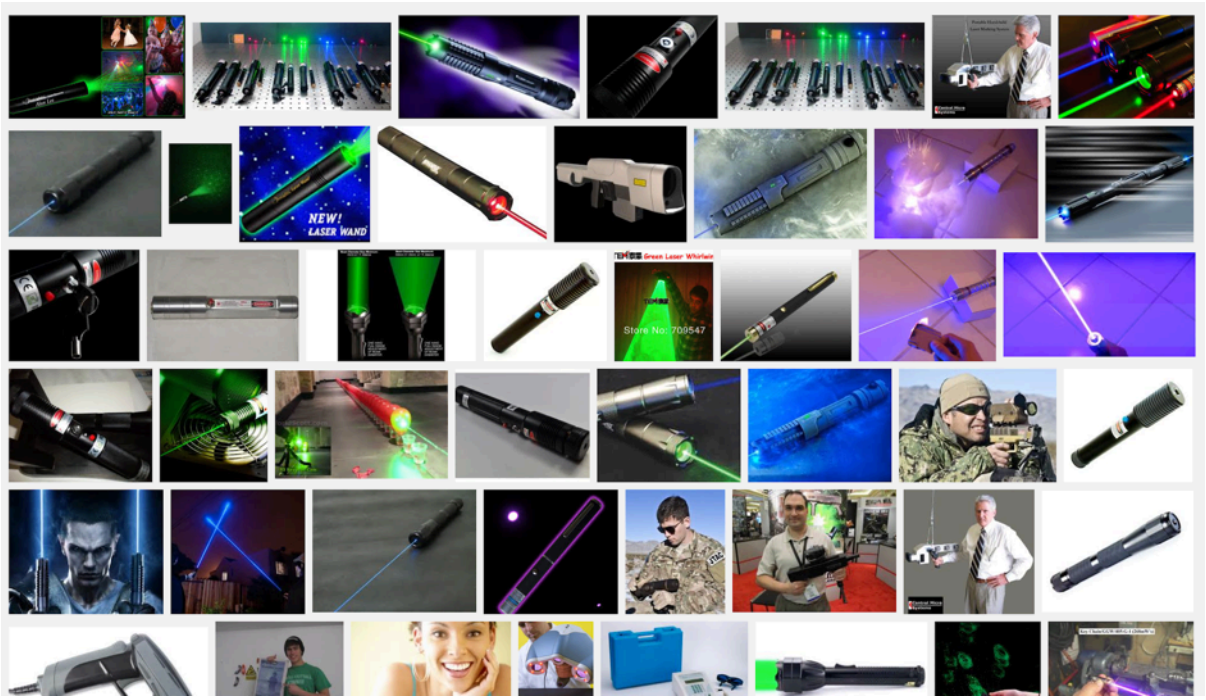


Note that the pictures show SLA lasers generally being on tripods or otherwise mounted onto fixed objects. Now compare these images to images of pointers and handhelds.

“LASER POINTER” GOOGLE IMAGE SEARCH:



“HANDHELD LASER” GOOGLE IMAGE SEARCH:



Almost all of the images of laser pointers and handhelds are of cylindrical devices similar to penlights or flashlights, roughly 1/4" to 1" in diameter. Clearly these are very different from most of the images of SLA lasers.

I do note that three or four of the alignment laser images show cylindrical lasers somewhat similar to pointers/handhelds. However, most of these include a mount by which the laser is not handheld but is fixed to an object or stand.

I also note that one photo of a surveying laser shows it being operated handheld. This laser is used for distance measurement. It has special circuits and features to perform this task, which are not in laser pointers or handhelds.

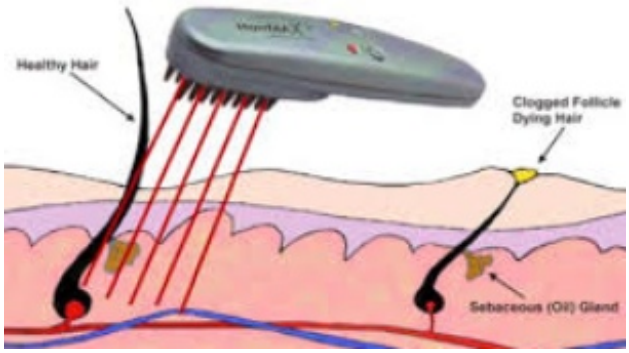
FDA IS NOT CORRECT ABOUT SOME CLAIMED FEATURES OF SLA LASERS

The May 5 2014 Draft Guidance has a list of six claimed features of SLA lasers. Let's review these to see if they are applicable to both SLA lasers and pointers/handhelds:

"Compact size (i.e. small, lightweight)"

Surveying and leveling lasers are not generally pocketable. Some alignment lasers are compact; note that these also require a mount for affixing to a tripod or surface. Pointers/handhelds are generally pocketable though a few are the size of larger flashlights.

> *Unique to SLAs and/or pointers?* No, there are some home medical lasers such as the Tria hair removal system, and the HandMax Laser Comb hair growth brush pictured below which are at least as compact as SLA lasers. There may be other compact laser systems; we have not done an exhaustive search.
>
> *Evaluation of FDA's claim:* Merely having a compact size does not make a laser product into an SLA laser.



“Battery power”

Yes, SLA lasers and pointers/handhelds are almost all battery powered.

> *Unique to SLAs and/or pointers?* No, there are other devices such as the hair removal and hair growth products which are also battery powered. Other battery-powered laser products include CD and DVD players.
>
> *Evaluation of FDA’s claim:* Merely being powered by batteries alone does not make a laser product an SLA laser.

“Ergonomic design to permit handheld use”

Most SLA lasers are not designed for handheld use, in two ways: 1) the physical size is too large for handheld use, as shown in many of the photos of surveying lasers, 2) an accurate measurement cannot be made if the laser is handheld.

(There is one exception: the beam of a surveying laser can be modulated to make handheld distance measurements. The photo below shows this use. Note that a pointer or handheld can NOT be used for this purpose, since the beam is not modulated and there is no distance circuitry or readout.)

> *Unique to SLA’s and/or pointers?* No, there are other types of products containing lasers which can be handheld. The medical hair removal/grown products discussed earlier are one type. Some embedded laser systems such as CD and DVD players also can be handheld.
>
> *Evaluation of FDA’s claim:* FDA is incorrect on this claim. Many SLA lasers are too large for handheld use, and almost all SLA lasers would not perform their function if handheld. The only type that could, distance-measuring lasers, are very different from pointers/handhelds since the latter cannot measure distances.

“An aperture in the laser product’s protective housing to transmit laser emission into open space”

FDA is correct that both SLAs and pointers/handhelds emit laser light into open space.

Unique to SLAs and/or pointers? However, there are many other types of lasers that emit into open space, including general-purpose lasers as well as many laboratory and industrial lasers. The medical hair lasers seen earlier are just one example.

Evaluation of FDA's claim: Many lasers have apertures which emit laser beams. Merely emitting a beam does not mean that a laser is used, or can be used, for SLA purposes.

"Portability to permit use in open spaces or in unrestricted environments"

As with having an aperture, many lasers -- including SLAs and laser pointers are portable and can be used in open spaces or in unrestricted environments. To give just one example, in the early days of laser light shows, glass-tube lasers six feet long with refrigerator-sized power supplies were used for outdoor shows. No one at FDA was claiming these were being used for surveying, leveling or alignment.

Unique to SLAs and/or pointers? SLA lasers are not the only type which are portable. Many lasers, including plug-in-the-wall lasers are light and small enough to be portable and could therefore be used in open spaces or unrestricted environments. Even medical lasers such as the hair removal/growth products are portable enough that they could permit use outdoors (though normally they would be stored or used indoors).

Evaluation of FDA's claim: Many lasers are portable. Merely being capable of use in open spaces or unrestricted environments does not mean that a laser is used, or can be used, for SLA purposes.

"Features that utilize the laser's straight line emission for surveying, leveling, or alignment"

This is a poorly worded claim. The FDA may be trying to say that any laser with straight line emissions (e.g., almost all lasers) could be used for surveying, leveling or alignment. This is not true unless the laser has other features enabling accurate measuring or alignment such as a stable mount.

Or, the FDA may be trying to say that an SLA product uses a laser's straight line emission for surveying, leveling or alignment -- which is a tautology: "An SLA laser uses a laser for SLA purposes."

Unique to SLAs and/or pointers? If we take the first meaning, the FDA appears desperate: They claim that any laser emitting a straight line is an SLA laser. Given that almost all lasers emitting light do so in straight lines (either as a narrow beam, or as a thin line or fan of light), this would mean that almost all lasers are SLA lasers. This is far too broad a claim.

If we take the second meaning, the FDA is defining SLA lasers as lasers used for SLA purposes, which is a circular definition.

Evaluation of FDA's claim: FDA's definition either includes almost all lasers, or only SLA lasers in a tautology. Either way the definition is useless for making regulatory distinctions.

FDA IS NOT CORRECT ABOUT CLAIMED FEATURES *NOT* IN SLA LASERS

Now let's look at FDA's list of features which they claim are NOT typical of an SLA laser.

"Predictable, stable power input and output" and "High quality power supply and/or power conditioning components"

I spoke with Dr. Charles Maricle of Aixiz Lasers, who supplies laser diodes to SLA manufacturers including Collimare, FMC and Global Industrial. His diodes have a built-in automatic current control driver. This allows the laser to be connected to a simple, unregulated power supply made by the manufacturer. He says the result is predictable, stable power output from the built-in power conditioning component: "They depend on me for a stable output laser."

So, at least some SLA lasers do have this feature (stable output, power conditioning components) which FDA claims is not typical of SLA lasers.

In addition, determining whether a laser is an SLA laser based on the quality of its power supply is likely to not be very relevant or accurate.

"Adjustability of power and wavelength"

I concur with FDA here, that in general SLA lasers and pointers/handhelds have a fixed optical (beam) power and one (or a very limited selection) of wavelengths. But note that many other types of lasers also have a non-adjustable power and wavelength -- this is not exclusive to SLAs and pointers/handhelds.

"Design that facilitates remote actuation"

I am not sure what FDA means by this. Perhaps they mean that most SLA lasers are not remotely operated. Actually, remote actuation and control of SLA lasers appears to be fairly common. A Google Image search brought up a number of "surveying laser remote controls":

A brief Google search for surveying laser remote control operating instructions revealed that the surveying remote controls include laser on/off and laser positioning buttons. A search for “leveling” and “alignment” remote controls had similar results.

I am not aware of any pointers or handheld lasers with a remote control, with the exception of the Wicked Laser EVO ($149 for 75 mW of green light), which has a “SmartPort” that allows control by an iPhone or Android app.

So, it appears FDA may be in error about SLA lasers not having remote actuation.

“Non-portability”

This is simply the flip side of FDA’s claim that SLA lasers are portable. As discussed earlier, in the past some bulky lasers have been used in open spaces and unrestricted environments for entertainment use. (Now that entertainment lasers are much smaller -- roughly breadbox-sized -- they are easier to use outdoors.)

Whether a laser is portable or not portable, is not particularly relevant to determining whether it is an SLA laser or not.

“Hard wire connection to power mains”

And this is simply the flip side of being battery powered. Yes, it is likely that SLA lasers and pointers/handhelds are not hard-wired to power mains. But this does not logically lead to the conclusion that all battery powered lasers are SLA lasers.

SUMMARY OF FDA-CLAIMED SLA DESIGN FEATURES

The following charts summarize the last two sections. Most FDA claims are found to be not entirely correct or are not specific to SLA laser products.

Design features claimed to be specific to SLA lasers	
Compact size (i.e. small, lightweight)	NOT ENTIRELY CORRECT: Many surveying and leveling lasers are shown by the Google Image search to be not of compact size (at least, not a pocketable size). Similarly, some high-powered flashlight-sized handheld lasers are large enough that they are not pocketable, and thus may not be considered compact. NOT SPECIFIC TO SLAs: Other types of laser products may have a compact size without being SLA lasers (home medical lasers, CD & DVD players).
Battery power	NOT SPECIFIC TO SLAs: While most SLA and pointers/ handhelds are battery powered, this is not specific to SLA lasers. Other types of laser products may also be battery powered without being SLA lasers (home medical lasers, CD & DVD players).
Ergonomic design to permit hand-held use	NOT ENTIRELY CORRECT: Many surveying and leveling lasers are shown by the Google Image search to not permit use while hand held, or to be non-ergonomic and thus uncomfortable when hand held. NOT SPECIFIC TO SLAs: Other types of laser products may have an ergonomic design permitting holding in the hand, without being SLA lasers (home medical lasers, CD & DVD players).
An aperture in the laser product's protective housing to transmit laser emission into open space	NOT SPECIFIC TO SLAs: Many other types of laser products have apertures to transmit laser emission into open space. Simply transmitting a beam does not make a laser product as manufactured, designed or intended for one or more SLA uses.
Portability to permit use in open spaces or in unrestricted environments	NOT SPECIFIC TO SLAs: Many other types of laser products are portable enough that they can be used in open spaces or unrestricted environments. Simply being portable does not make a laser product as manufactured, designed or intended for one or more SLA uses.
Features that utilize the laser’s straight line emission for surveying, leveling, or alignment	NOT A CLEAR DEFINITION: This can be read as stating that lasers emitting straight lines can be used for SLA purposes (in which case almost all lasers would be SLAs, which is nonsense), or it can be read as stating that SLA lasers use the laser’s straight line emission for SLA purposes (which is then a circular definition).

Design features claimed to be NOT typical of an SLA laser	
Predictable, stable power input and output	APPEARS TO BE INCORRECT: A diode manufacturer says his diodes sold for SLA products have built-in power conditioning that provides predictable, stable power output. NOT SPECIFIC TO SLAs: Other laser products may or may not have stable power output, high-quality power supplies, or power conditioning components. The presence or absence of these features alone would not indicate whether a laser is manufactured, designed or intended for SLA uses.
High quality power supply and/or power conditioning components	See above.
Adjustability of power and wavelength	NOT SPECIFIC TO SLAs: Many laser products other than SLAs have a non-adjustable power and wavelength. This alone would not indicate whether a laser is manufactured, designed or intended for SLA uses.
Design that facilitates remote actuation	APPEARS TO BE INCORRECT: A Google search turns up many SLA laser products with remote controls that include turning the laser on and off remotely.
Non-portability	NOT SPECIFIC TO SLAs: This is the mirror image of the "Portability" design feature. As discussed, many laser products are portable, so portability or non-portability is not a distinguishing feature of SLA lasers.
Hard wire connection to power mains	NOT SPECIFIC TO SLAs: This is the mirror image of the "Battery power" design feature. As discussed, many laser products are hard wired, so battery or mains power is not a distinguishing feature of SLA lasers.

LOGICAL FALLACY:
IF A SURVEYOR IS A PERSON, THEN ALL PEOPLE ARE SURVEYORS

Beyond problems with specific claimed design features, FDA is making a basic logical error. They are cherry-picking only certain features of SLA lasers, and then claiming that any lasers with those features are SLA lasers. FDA has picked some very common design features -- compact size, battery power, beam into open space, straight line beam -- and is attempting to say that a laser with these features is therefore manufactured, designed or intended for surveying, leveling or alignment uses.

As stated earlier, this would be like saying "Medical lasers' design features include large size, wall-powered, being bulky, and emitting a straight line. Therefore, lasers having these features are evidence that the product was manufactured, designed, intended or promoted for medical use, and they will fall under FDA jurisdiction." It is a logical fallacy and is complete overreaching.

SLA LASERS ARE ALREADY CLEARLY DEFINED IN 21 CFR 1040.10

FDA does not need to define SLA lasers by making up dubious claims about design features. SLA lasers are already clearly defined by existing regulations, in 21 CFR 1040.10(b)(39):

Surveying, leveling, or alignment laser product means a laser product manufactured, designed, intended or promoted for one or more of the following uses:

(i) *Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement.*
(ii) *Positioning or adjusting parts in proper relation to one another.*
(iii) *Defining a plane, level, elevation, or straight line.*

Note that this definition of SLA laser usage relies on the actual use of the laser -- not on its size, or whether it emits a straight beam, or whether it is battery powered.

A detailed reading of the 21 CFR definition supports the concept that using a laser to point out things is very different from using a laser for surveying, leveling or alignment, for the following reasons:

(i) A laser used for pointing is NOT measuring anything. It also is not determining or delineating the form, extent or position of a point, body, or area by taking angular measurement.
(ii) A laser used for pointing is NOT positioning or adjusting parts or anything else.
(iii) A laser used for pointing is NOT defining a plane, level or elevation. It also is NOT defining a straight line.

I have been told that when CDRH first went to regulate pointers, they concluded that pointers were “determining … the position of a point” that was of interest to the lecturer and audience. But this is incorrect. The lecturer and audience are NOT trying to determine where the point is, in the sense of measuring, surveying, leveling or aligning. They certainly are not “taking angular measurement”. They simply are using the laser’s dot to call attention to a location.

I was also told that CDRH concluded that lasers were “defining a … straight line.” Again, this is an incorrect interpretation for pointing applications, for two reasons:

- Often a pointer’s beam is so weak that it cannot be seen in mid-air. Only the dot at the end of the beam is visible when it is on a surface. In such a case, there is no beam and thus no straight line at all.

- Even if the laser’s beam can be seen, it is not being used to “define” a line. The presenter and the audience are not interested in the line per se. They are interested in what the line is pointing at.

A final, fatal blow to the “straight line” interpretation is the fact that almost all lasers create straight lines. This does not mean FDA can regulate selected or all laser uses based on this fact. If so, Congress would simply have given FDA authority over any laser that could create a straight line. But 21 CFR 1040.10(b)(39)(iii) is part of a limited grant of authority, first over “surveying, leveling or alignment” uses and second only over applications where the laser product DEFINES a straight line – not IS a straight line.

In summary, even a cursory reading of the uses being defined – “surveying, leveling or alignment” – cannot support the argument that pointing at an object is surveying, is leveling or is alignment. If this was correct, then a person thrusting their outstretched arm at an object and saying “look over there” would somehow be involved in surveying, leveling, alignment, angular measurement, positioning parts or defining a straight line. But this is simply not true.

THE DRAFT GUIDANCE SHOULD NOT BE ISSUED

This comment has primarily addressed Question 3 in FDA’s May 5 2014 Draft Guidance. I believe that the claims in Question 3 are not valid for regulatory purposes, and thus the entire Draft Guidance should be struck.

For example, Question 4 about a class limit on SLA lasers would not be necessary since there already is a definition of SLA lasers in 21 CFR 1040.10. Any lasers defined as SLA under that definition would have a class limit imposed (by 21 CFR 1040.11(b).

Also, Question 5, about promoting lasers for general-purpose uses, would not be necessary. If a laser product is not manufactured, designed, intended or promoted for the specific SLA uses defined in 21 CFR 1040.10(b)(39), and if it is not a demonstration or medical laser, then it is a general-purpose laser. FDA cannot go beyond what is clearly in 21 CFR 1040.10.

Assuming the Draft Guidance is not issued, then I have the following recommendations:

- Laser pointers should continue to be regulated as demonstration lasers (for historical reasons)
- Handheld lasers (those above 5 mW) should not have restrictions beyond those already applied for their Class, as long as they are not manufactured, designed, intended or promoted for pointing purposes.
- If FDA wants to regulate the types of lasers listed in Question 2 of the Draft Guidance, they need to seek explicit Congressional authority (or at the very least, not try to shoehorn these laser types into the already-clearly defined category of SLA uses).

I note that in the past FDA has used the Draft Guidance definition of SLAs in order to try to regulate certain lasers. An example is the November 29, 2012 warning letter sent to Laser Energetics, Inc. which states that a laser dazzler is an SLA product because it is "designed to transmit laser radiation through open space for measuring and positioning purposes". Based on this, I have the following additional recommendation:

- Any past actions FDA has taken against products due to claimed SLA status, when in fact the product is not used for surveying, leveling or alignment as described in 21 CFR 1040.10(b)(39)(iii), should not be upheld. Of course, this only applies to FDA claims of being an SLA product. If there are other problems with the product such as mislabeling or not filing a product report, these actions should be upheld if valid.

WHY THIS COMMENT

I was asked by a respected laser safety official why I oppose the May 5 2014 Draft Guidance -- even if I might personally agree that additional controls over laser pointers and handhelds may be necessary. I would like to address this question.

One reason is that I respect plain English language. I believe regulatory actions should be based on what is clearly written in laws and regulations, or else new laws should be passed.

21 CFR 1040.10 already has an accurate description of SLA laser products, based on how they are used. A Guidance document should not extend this definition based on nebulous, cherry-picked design features that may or may not be present in SLAs or in the proposed regulatory extension (e.g., to laser pointers and other types). This is not guidance; this is a new regulation based on very shaky premises.

Further, I must object to misuse of logic. As stated numerous times, because Product X has certain characteristics does not mean that all other products with those characteristics can be regulated as if they were Product X.

Finally, I point to the fact that none of the pointer/handheld features -- pointing per se, battery power, compact size, portability, etc. -- are referred to in 21 CFR 1040.10. It is hard to understand how these features can be used to regulate, if they are not even mentioned as factors in existing law.

While I greatly appreciate FDA staff's workload and cleverness in trying to regulate handheld lasers and other types, my conclusion is that FDA clearly does not have the authority to regulate laser products that are not manufactured, designed, intended or promoted for demonstration, SLA or medical purposes.

If FDA feels it is necessary to control laser pointers, handheld lasers and other types, then they should seek new federal legislation addressing this point. (I would also

request that they ask for permission to require a “Laser Safety Facts” label similar to those described at LaserSafetyFacts.com, just as FDA currently requires Nutrition Facts and Drug Facts labels. At the very least, pointer/handheld labels should warn against aiming at aircraft.)

Many other countries’ legislatures have passed bills that ban or more severely regulate pointers and handhelds. If the U.S. feels this is necessary, the details should be debated and drawn up by the legislature -- not by a clever but ultimately incorrect and illogical twisting of the already clear SLA language in 21 CFR 1040.10.

[end of main body of comments; remainder of this page deliberately left blank]

APPENDIX: AUTHOR'S BACKGROUND

I am the sole editor and webmaster of LaserPointerSafety.com, a comprehensive, independent website to help consumers safely use laser pointers and handheld lasers. I also compile news about misuse events — both eye injuries and aviation incidents. So I have been closely following the spread of lasers to consumers, and the resulting increase in laser pointer and handheld misuse.

In addition to this work, I have also been an active member since the mid-1990s of the SAE G10-T Laser Hazards Subcommittee. I have participated in the committee's drafting of policies and recommendations which were eventually adopted by the FAA. Recently I wrote draft guidance for pilots for the FAA; I understand this is undergoing review and revisions within the Agency.

Below is a biographical sketch:

> Patrick Murphy holds a B.A. degree in Laser Art and Technology from Oberlin College (1981) and an MBA degree from the Keller Graduate School of Management (2006). In 1986 he founded Pangolin Laser Systems, which became a leader in the field of software for laser light shows and displays. He served as President of the International Laser Display Association (ILDA) during 1996, was Airspace Issues Coordinator for ILDA from 1996 to 1999, and has served as executive director of ILDA since 2006. *[Note that this comment is being submitted as a private citizen and does not represent any ILDA position or policy.]*
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> Murphy is a representative from ILDA to the SAE G10T Laser Safety Hazards Committee, the primary group working on laser/aircraft safety issues. In this capacity, he has helped to write regulations and forms used by the U.S. Federal Aviation Administration for evaluating outdoor laser shows. In 2000 he received an Award of Recognition from SAE G10T for this work, and an ILDA Certificate of Commendation. In 2004 he received ILDA's highest honor, the Career Achievement Award.
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> He has presented papers at the International Laser Safety Conference, in 1997, 2009 and 2011, on the topics of laser/aircraft safety and audience-scanned laser shows. In 2009 he was the invited guest speaker at the 14th Annual Laser Safety Forum at Loughborough University in the U.K. In 2011, he received a Certificate of Appreciation from SAE G10T for work on Aerospace Standard 6029, "Performance Criteria for Laser Control Measures Used for Aviation Safety."
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> In October 2011, he was invited by the Air Line Pilots Association to speak at a major Washington D.C. conference held to publicize laser illumination hazards. In July 2012, he was invited by the Airborne Law Enforcement Association to speak at their annual conference in Reno, NV. During 2013, he helped write the FAA's Laser Beam Exposure Questionnaire and an FAA document (in draft) summarizing laser hazards and mitigation for pilots.