Illuminating the Hazards of Powerful Laser Products

Lecturers use laser pointers to draw attention to information on charts and slides. Construction workers use lasers to level and align pipes. Entertainers use laser projectors to create dazzling light shows. These are legitimate uses of lasers.

FDA / Zebulon Rogerson

When used responsibly, lasers are safe. However, a powerful laser, used irresponsibly, is unsafe, particularly when misused as a toy or directed at people, vehicles, or aircraft.

What makes lasers potentially dangerous?

- The light energy from a laser aimed into the eye can be hazardous, perhaps even more so than staring directly into the sun.
- The startling effect of a bright beam of light can cause serious accidents when aimed at a driver in a car, a pilot in a plane, or even a person holding a cup of hot coffee.

Powerful and Unsafe

The Food and Drug Administration (FDA) is concerned about the increased availability in stores and on the Internet of certain types of laser products—some of which are being sold illegally because they are powered above 5 milliwatts (mW), which is a standard for certain types of lasers and laser projectors.

Manufacturers of some types of laser products that are powered above 5 mW must obtain permission from FDA before they are sold to the public. This power limit applies to lasers sold to the public for purposes of alignment, surveying, or leveling, and includes lasers used for pointing. Laser projectors powered above 5 mW and the laser light shows that they produce must also be manufactured with permission from FDA.

Green lasers are particularly troubling to FDA, says CDR Dan Hewett, U.S. Public Health Service, a health promotion officer in the Electronic Products Branch of FDA's Center for Devices and Radiological Health.

"A green laser beam could cause a larger startling or flash-blinding effect compared to a similarly powered red laser because the human eye is espe-

cially sensitive to green light," says Hewett. Flash blindness is a temporary loss of vision that occurs when the eye is suddenly exposed to intense light. The effect can last from several seconds to several minutes.

"As technology has evolved, lasers have increased rapidly in power and decreased in size and power consumption," says Hewett. "Laser use in consumer products is increasing rapidly, and that demand has pushed the price of powerful lasers lower. As the price goes down, more people may acquire powerful, unsafe lasers, creating more opportunity for misuse and injury."

Hewett emphasizes the reason for the 5 mW limit. "A 5 mW laser aimed directly into the eye won't cause damage instantaneously. A person's reflexes to look away, blink, or make other involuntary movements are protective. But if you keep your eyes open and stare into a 5 mW beam, it will cause damage. A higher-powered laser gives you less time to look away before injury can occur, and as power increases, eye damage may happen in a microsecond, even when looking at a beam reflection."

Lasers Pointed at Aircraft on the Rise

Laser lights beamed at aircraft also have FDA concerned. Incidents associated with laser lights beamed at aircraft have tripled in a 4-year period since December 2004, when the Federal Aviation Administration began tracking reports. In 2008, pilots reported a total of 950 cases of laser light striking an aircraft or illuminating a cockpit.

Eye injuries and flash blindness from laser beams hitting aircraft are also on the rise, with more pilots self-reporting injuries in 2008 than in the previous 3 years combined. The distraction from flash blindness could cause a serious accident.

Tips for Consumers

- Never aim or shine a laser at anyone, including animals.
- Look for the following information on the label to make certain that a laser (or a toy that includes a laser) is safe:
  - a statement that it complies with Chapter 21 CFR (the Code of Federal Regulations)
  - the manufacturer's or distributor's name and the date of manufacture
  - a warning to avoid exposure to laser radiation
  - a class designation up to Class IIIa
- Be aware that the manufacturer of a Class IIIb or IV laser product must obtain permission (also called a "variance") from FDA before the laser is sold to the public if the laser product:
  - is designed, intended, or promoted for surveying, leveling, or alignment (which includes pointing)
  - is a demonstration laser product (which includes laser projectors) that is designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition

Surveying, leveling, or alignment laser products and demonstration laser products mentioned directly above that are powered above 5 mW with no label that indicates they were manufactured under a variance present a serious safety hazard and are not legal for sale!

Law enforcement agencies have the authority to arrest individuals who threaten the safety of others from laser misuse, and several of these individuals have been prosecuted under federal law.

FDA's Authority

FDA regulates radiation-emitting electronic products, including all types of lasers. The agency sets radiation safety product performance standards that must be met by manufacturers before laser products can be legally sold in the U.S. market.

FDA's authority extends to testing laser products and inspecting displays of laser light shows to ensure the public is protected. FDA may also inspect manufacturers of laser products ranging from high-powered telescopes for professionals to low-powered toys for consumers. FDA can require repair, replacement, or refund for products that don't comply with FDA standards or that have radiation safety defects. In addition to inspecting domestic manufacturers, FDA inspectors travel abroad to inspect foreign manufacturers of products that contain lasers.

"We have often found laser toys that have lasers for pointing that are powered above 5 mW," says Hewett. "Sometimes toys or other laser products are powered above 5 mW after the batteries that come with them are replaced with fresh batteries."

"Some of the companies we inspect have very sophisticated testing to make sure the products for public sale are not powered above the 5 mW Class IIIa limit," says Emir Galevi, an FDA electronics engineer who does many of the foreign inspections. "But others are garage-based packing and distribution operations with inadequate testing procedures."

FDA may send a warning letter to manufacturers, put a company or product on an import alert (which notifies inspectors to stop product shipments at the border), or take other action if a firm lacks proper quality control for its laser products.

Illegal laser products that are imported are also subject to detention and seizure by U.S. Customs and Border Protection. "The problem is that

many of these illegal lasers come into the country through circuitous routes involving multiple distributors and multiple countries," says Galevi. "Or they're ordered one at a time through the Internet, which makes it difficult to track and stop them."

FDA is working to discourage online sales of illegal lasers and online video demonstrations that describe how to modify a laser pointer to make it more powerful.

FDA requires that labeling on most laser products contain a warning about radiation and other hazards and a statement certifying that the laser complies with FDA safety regulations. The label must also state the product's output power and hazard class (see table).

This article appears on FDA's Consumer Updates page (*www.fda.gov/ForConsumers/ConsumerUpdates/default.htm*), which features the latest on all FDA-regulated products.

Laser Hazard Classes

The Food and Drug Administration (FDA) recognizes four major hazard classes (I to IV) of lasers, including three subclasses (IIa, IIIa, and IIIb). The higher the class, the more powerful the laser and the potential to pose serious danger if used improperly. The labeling for Classes II–IV must include a warning symbol that states the class and the output power of the product. Approximate IEC equivalent classes are included for products labeled under the classification system of the International Electrotechnical Commission.

Class FDA	Class IEC	Laser Product Hazard	Product Examples
I	1, 1M	Considered non-hazardous. Hazard increases if viewed with optical aids, including magnifiers, binoculars, or telescopes.	• laser printers • CD players • DVD players
IIa, II	2, 2M	Hazard increases when viewed directly for long periods of time. Hazard increases if viewed with optical aids.	• bar code scanners
IIIa	3R	Depending on power and beam area, can be momentarily hazardous when directly viewed or when staring directly at the beam with an unaided eye. Risk of injury increases when viewed with optical aids.	• laser pointers
IIIb	3B	Immediate skin hazard from direct beam and immediate eye hazard when viewed directly.	• laser light show projectors • industrial lasers • research lasers
IV	4	Immediate skin hazard and eye hazard from exposure to either the direct or reflected beam; may also present a fire hazard.	• laser light show projectors • industrial lasers • research lasers • lasers used to perform LASIK eye surgery

For More Information

Frequently Asked Questions About Lasers
www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/LaserProductsandInstruments/ucm116362.htm

Consumer Safety Alert: Internet Sales of Laser Products
www.fda.gov/Radiation-EmittingProducts/RadiationSafety/AlertsandNotices/ucm116534.htm

Reporting Unlawful Sales of Medical Products on the Internet
www.fda.gov/Safety/ReportaProblem/ucm059315.htm