

SAFEGUARDS

CONSUMER GOODS AND RETAIL

TOYS & JUVENILE PRODUCTS

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US FDA ISSUES DRAFT GUIDANCE FOR CHILDREN'S TOY LASER SAFETY

On 7 August 2013 the US Food and Drug Administration (FDA) issued a proposed rule to define children's toy Light Amplification by Stimulated Emission of Radiation (laser) products and require them to be within International Electrotechnical Commission (IEC) Class 1 emission limits. The 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 greater the potential to pose serious danger if used improperly.

Under this proposed rule, designation of proper labeling with statements indicating compliance with 21 CFR Subchapter J on the label is highly encouraged.

The highly-concentrated light emitted from lasers, even those in toy laser products, can be dangerous resulting in serious eye injuries and even blindness, not just to the person using a laser, but to anyone within range of the laser beam when operated unsafely or without certain controls. For laser toys to pose minimum risk to users, the levels of laser radiation or light output must not exceed the emission levels for Class I as defined in the Federal Performance Standard for Laser Products or for Class 1 as defined by the International Electrotechnical Commission (IEC).

Although most children's toy laser products would meet the definition of "demonstration laser products" or "surveying, levelling, and alignment laser products" specified in the US Code of Federal Regulations at 21 CFR 1040.10(b)(13) and (39), and thus have to comply with the limits at 21 CFR 1040.11(b) or (c), at present FDA regulations do not specifically address children's toy laser products.

The Food and Drug Administration (FDA) is particularly concerned about the potential danger to children and those around them, and has issued a [draft guidance document](#) on the safety of toy laser products. For purposes of this guidance, "children's toy laser product" means a product that is manufactured, designed, intended or promoted for use by children under 14 years of age and they are covered under the scope of this guidance document.

Following are examples of children's toy laser products included in the guidance document:

- Lasers mounted on toy guns that can be used for "aiming";
- Spinning tops that project laser beams while they spin;



- Hand held lasers used during play as "light sabers";
- Dancing laser beams projected from a stationary column; and
- Lasers intended for entertainment that create optical effects in an open room.

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Manufacturers of laser products are responsible for compliance with all applicable requirements of Title 21 Code of Federal Regulations (Subchapter J, Radiological Health) Parts 1000 through 1005.

In addition, laser products must comply with radiation safety performance standards in Title 21 Code of Federal Regulations (Subchapter J, Radiological Health) Parts 1010 and 1040.

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FOR ENQUIRIES:

Global Competence Support Centre:
gcsc@sgs.com

US-Ali Karimi , Tel: + 973-461-7928 or
Ali.Karimi@sgs.com

Asia – Hong Kong,
Tel: +852 2334 4481,
mktg.hk@sgs.com

Australasia – Perth.
Tel: +61 (0) 3 9790 3418
au.cts@sgs.com

Europe – London – UK.
Tel: +44(0) 203 008 7860
gb.cts.sales@sgs.com

Africa & Middle East – Turkey.
Tel: +90 212 368 40 00
sgs.turkey@sgs.com

Americas – USA.
Tel: +1 973 575 5252
uscts.inquiries@sgs.com

www.sgs.com/cgnr

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