Minimizing Risk for Children's Toy Laser Products

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 19, 2014

The draft of this document was issued on August 7, 2013.

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Food and Drug Administration
Center for Devices and Radiological Health

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Division of Radiological Health
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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2012-D-1092. Comments may not be acted upon by the Agency until the document is next revised or updated.

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This guidance is intended to inform manufacturers of laser products, FDA staff and the public of the Center for Devices and Radiological Health's (CDRH) current thinking on the safety of children's toy laser products. Lasers with outputs above certain levels that are operated in an unsafe and uncontrolled manner may cause injury to the user and/or others within range of the laser beam. This is a particular concern for lasers intended for entertainment purposes, especially when intended to be used as toys by children.

Federal law requires that, other than for certain exceptions, laser products manufactured or assembled after August 1, 1976 must be in compliance with the Federal Performance Standards for Laser Products (21 Code of Federal Regulations (CFR) 1040.10 and 1040.11). At present FDA regulations do not specifically identify what constitutes children's toy laser products. In June 2013, FDA issued a proposed rule that proposed to define children's toy laser products and require them to be within the International Electrotechnical Commission (IEC) Class 1 emission limit.[1] While this rulemaking process is ongoing, CDRH recommends that manufacturers keep children's toy laser products within the FDA Class I or IEC Class 1 emission limits in order to minimize the risk they pose to users and/or others in range of the laser beam, including the vulnerable population for whom they are intended.[2]

[1] See proposed 21 CFR 1040.10(b)(1), (2) and 1040.11(d) at 78 FR 37723 (June 24, 2013).

[2] For those children's toy laser products that meet the definition of a "demonstration laser product" or "surveying, leveling, or alignment laser product," CDRH will not object to compliance with the

This guidance, in question and answer format, is derived from questions CDRH has received from persons in industry, the public, and other stakeholders.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

Children's Toy Laser Products

1. Question: Why is CDRH concerned about the use of laser products?

Answer: FDA has statutory authority to regulate radiation-emitting electronic products pursuant to sections 531 through 542 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. §§ 360hh - 360ss). Federal law requires that, other than for certain exceptions, laser products manufactured or assembled after August 1, 1976 must be in compliance with the Federal Performance Standards for Laser Products (21 CFR 1040.10 and 1040.11). Lasers products may be used in unsafe or uncontrolled ways and can cause injury to the user and/or others in range of the laser beam. Accordingly, FDA requires that manufacturers of these products incorporate safety features, warnings, and instructions for safe use(see 21 CFR 1040.10 and 1040.11).

2. Question: What types of lasers fall within the scope of this guidance document?

Answer: Any toy that constitutes, incorporates or is intended to incorporate a laser or laser system is a laser product. See 21 CFR 1040.10(b)(21). As stated above, laser products are subject to the Federal Performance Standards for Laser Products contained in 21 CFR 1040.10 and 1040.11. For purposes of this guidance, "children's toy laser product" means a product primarily used as a toy that is manufactured, designed, intended or promoted for novelty or visual entertainment use by children under 14 years of age.

This definition is intended to exclude laser products that are used in professional or academic settings that may be used by children (for example, laser printers, CD players, educational and science kits). This guidance provides CDRH's current thinking on what constitutes

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International Electrotechnical Commission Class 1 emission limit (set forth in IEC 60825-1:2007). To that end, this guidance supersedes in part the policy set forth in the Guidance on Laser Products – Conformance with IEC 60825-1 and IEC 60601-2-22 (Laser Notice No. 50) (June 2007), available at http://www.fda.gov/downloads/MedicalDevices/.../ucm094366.pdf, which will cease to be effective by its own terms upon the effective date of amendments to the regulations applicable to laser products. However, because IEC Classes 1M and 2M do not have comparable analogs in FDA's classification system, manufacturers should not conform to the parameters for IEC Classes 1M or 2M unless they also comply with FDA's performance standards for laser products.

children's toy laser products, as well as specific safety recommendations for their manufacture and labeling.

When assessing whether a laser product is a children's toy laser product within the scope of this document, CDRH considers the following information:

- Promotion, advertising, labeling, packaging, and product graphics – For example, advertisements, especially in children's publications or other media, showing a child playing with the product or otherwise suggesting the product is intended for a children's novelty or child's visual entertainment use, would generally indicate it is a children's toy laser product. Pictures on packages or labels showing play with the product, especially when cartoon characters make the product attractive to children, would also generally indicate it is a children's toy laser product.
- Location of product sales – For example, sales in toy stores or other settings specifically geared towards children's entertainment, would generally indicate it is a children's toy laser product.
- Purpose of the product – Features or the nature of the product itself may indicate it is intended for use by children.

CDRH may use this and other information to identify a children's toy laser product, and engage manufacturers in discussions or investigations related to product safety.

The following are examples of children's toy laser products:

- 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 with bright colors or pictures on the box that might appeal to children; and
- Lasers intended for entertainment that create optical effects in an open room with bright colors or pictures on the box that might appeal to children.

3. Question: Why is CDRH concerned in particular about children's toy laser products?

Answer: CDRH believes that toys containing lasers and lasers marketed as toys are particularly susceptible to being used in an unsafe or uncontrolled manner. All children's toy laser products should "minimize risk" (refer to Q&A #4). Due to the nature of children's toy laser products, the dangers of these products may not be evident to children or the adults supervising them. Retinal injuries caused by laser light may go unnoticed and unreported in part because the retinal injuries may not be evident. Lasers can also cause skin burns.

4. Question: What is meant by "minimize risk" as used in this guidance?

Answer: A children's toy laser product in which the levels of laser radiation or light output exceed the emission levels for Class I as defined in the Federal Performance Standard for Laser Products ("FDA Class I") (21 CFR 1040.10 and 1040.11) or for Class 1 as defined by the International Electrotechnical Commission (IEC) ("IEC Class 1") under conditions of operation, maintenance, service, failure, or breakage do not "minimize risk" to users. Because children's toy laser products are not specifically identified in the Federal Performance Standard, manufacturers may not think they have to comply with the current standard, and consequently certain children's toys may contain lasers with power limits that pose a significant risk to eyesight. As discussed above, FDA published a proposed rule that includes a new section to specifically identify what constitutes children's toy laser products. See 78 FR 37723, 37741 (June 24, 2013). This new section, as proposed, includes the definition of a children's toy laser product and requires that the emissions of children's toy laser products not exceed the IEC Class 1 limit.

5. Question: Why does CDRH believe the emission limit of IEC Class 1 sufficiently limits risk for children's toy laeser products?

Answer: CDRH recognizes that IEC Class 1 has a higher power limit than FDA Class I. CDRH has determined that lasers with emissions under either the FDA Class I or IEC Class 1 limit sufficiently minimize risk, even when these products are used by children. As stated in IEC 60825-1:2007, Annex C.2, IEC Class 1 lasers are "Laser products that are safe during use, including long-term direct intrabeam viewing, even when exposure occurs while using optical viewing instruments (eye loupes or binoculars)." Output levels in excess of the IEC Class 1 limit are not necessary for the intended functions of toys – toys with lasers under this limit produce the intended visible laser light while still sufficiently minimizing risk.

6. Question: Does CDRH recommend a Class 1 label for children's toy laser product within IEC Class 1 limits?

Answer: Yes. IEC Class 1 designation labeling is recommended because CDRH believes the presence of this designation in the labeling would clearly advise purchasers that the products sufficiently "minimize risk" (refer to Q&A #4) and have been certified as such by the manufacturer. Such designation would indicate that the product is not in a higher emission level laser class, and that the safety controls and warnings required for higher class lasers are unnecessary for the product.

7. Question: For toys that contain parts that emit laser light, does the entire toy need to be certified?

Answer: The entire toy needs to be certified as a laser product, unless the part or parts of the toy that can emit laser light are removable and can emit laser light independently when separated from the other parts of the toy, in which case only those laser-emitting part or parts would need to be certified. For example, a laser gunsight that is detachable from a toy gun is

itself subject to applicable laser safety regulations and must be certified because it is a removable laser system (see 21 CFR 1040.10(c)(2)). The requirement for a certification is based on the removable laser's class, which is based on the accessible emission of laser radiation when the laser is removed. 21 CFR 1040.10(c)(2).

8. Question: Toys are regulated by the Consumer Product Safety Commission (CPSC). Why is CDRH providing this guidance when the CPSC already regulates toys?

Answer: Toys may be subject to laws administered by the CPSC, such as the Consumer Product Safety Act (15 U.S.C. §§ 2051 - 2089), as amended by the Consumer Product Safety Improvements Act of 2008 (Pub. L. 110–314, 122 Stat. 3016 (2008)), and the Federal Hazardous Substances Act (15 U.S.C.§§ 1261 - 1278a). FDA has statutory authority to regulate radiation-emitting electronic products, such as laser products, pursuant to sections 531 through 542 of the FD&C Act (21 U.S.C. §§ 360hh - 360ss). In the case of children's toy laser products, CPSC and FDA authorities complement one another to minimize the risk from using these products and facilitate compliance by manufacturers.