DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1092]

Minimizing Risk for Children's Toy Laser Products; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Minimizing Risk for Children's Toy Laser Products.'' This guidance is intended to inform manufacturers of laser products, FDA headquarters and field personnel, and the public of the Center for Devices and Radiological Health's (CDRH) current thinking on the safety of children's toy laser products and to provide specific safety recommendations for the manufacture and labeling of children's toy laser products.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Minimizing Risk for Children's Toy Laser Products'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Hewett, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4250, Silver Spring, MD 20993–0002, 301–796–5864.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance is intended to inform manufacturers of laser products, FDA headquarters and field personnel, and the public of CDRH's 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 CFR 1040.10 and 1040.11). At present FDA regulations do not specifically identify what constitutes children's toy laser products. In the **Federal Register** of June 24, 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 (see proposed 21 CFR 1040.10(b)(1), (2) and 1040.11(d) at 78 FR 37723 (June 24, 2013)). 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. 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 International Electrotechnical Commission Class I 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), which will cease to be effective by its own terms upon the effective date of amendments to the regulations applicable to laser products. (Ref. #1). 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.

In the **Federal Register** of August 7, 2013 (78 FR 48172), the Agency issued the draft guidance entitled ''Minimizing Risk for Children's Toy Laser Products—Draft Guidance for Industry and Food and Drug Administration Staff.'' The Agency received two comments on the 2013 draft guidance and has incorporated most of the recommendations in this final guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on children's toy laser products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Minimizing Risk for Children's Toy Laser Products'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1810 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to a previously approved collection of information found in FDA regulations. This collection of information is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in part 1040 is approved under OMB control number 0910–0025.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and

will be posted to the docket at *http://www.regulations.gov.*

VI. References

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. FDA 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.*

Dated: December 15, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0128] (Formerly Docket No. 2007D–0396)

Serious Drug-Induced Liver Injury: The Importance of Getting It Right: How To Measure and Interpret Drug-Induced Liver Injury Information and Make Correct Diagnoses; Public Conference; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public conference entitled ''Serious Drug-Induced Liver Injury (DILI): The Importance of Getting It Right: How to Measure and Interpret DILI Information and Make Correct Diagnoses.'' This conference will be cosponsored with the Critical Path Institute (C-Path) and the Pharmaceutical Research and Manufacturers of America. The purpose of the public conference is to discuss, debate, and share views among stakeholders in the pharmaceutical industry, academia, health care providers, patient groups, and regulatory bodies on how best to detect and assess the severity, extent, and likelihood of drug causation of liver injury and dysfunction in people using drugs for any medical purpose.

DATES: The public conference will be held on March 18, 2015, from 8 a.m. to 6 p.m. and on March 19, 2015, from 8 a.m. to 4 p.m.

ADDRESSES: The public conference will be held at the College Park Marriott Hotel & Conference Center, 3501 University Blvd., Hyattsville, MD 20783. The hotel's phone number is 301–985–7300.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4478, Silver Spring, MD 20993–0002, 301–796–0518, email: *lana.pauls@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In July 2009, FDA announced the availability of a guidance for industry entitled ''Drug-Induced Liver Injury: Premarketing Clinical Evaluation'' (74 FR 38035, July 30, 2009). This guidance explains that DILI has been the most frequent cause of safety-related drug marketing withdrawals over the past 50 years and that hepatotoxicity has limited the use of many drugs that have been approved and has prevented the approval of others. It discusses methods of detecting DILI by periodic tests of serum enzyme activities and bilirubin concentration and how changes in the results of those laboratory tests over time, along with symptoms and physical findings, may be used to estimate severity of the injury. The guidance suggests some ''stopping rules'' for interrupting drug treatment and the need to obtain sufficient clinical information to assess causation. FDA published a draft of this guidance in 2006, and comments on the draft were taken into consideration when issuing the final guidance in July 2009. FDA is now interested in obtaining stakeholder input on the issues addressed in this guidance, including comments regarding potential revisions to the guidance.

II. Conference Information

The purpose of the 2015 conference is to invite participants to present their data and views, and to hold open discussion.

A. Registration

A registration fee ($600 for industry registrants and $300 for Federal government and academic registrants) will be charged to help defray the cost of renting the meeting space, providing meals and snacks, covering the travel fees incurred by invited academic (but not government or industry) speakers, and other expenses. The registration process will be handled by C-Path, an independent, nonprofit organization established in 2005 with public and private philanthropic support from the southern Arizona community, Science Foundation Arizona, and FDA.

Additional information on the conference, program, and registration procedures may be obtained on the Internet at *http://www.c-path.org* and *http://www.fda.gov* by typing ''liver toxicity'' into the search box. (FDA has verified the C-Path Web site address but is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

B. Transcripts

Please be advised that as soon as a transcript is available of the public conference, it can be obtained in either hardcopy or on CD–ROM after submission of a Freedom of Information Act (FOIA) request. Written FOIA requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Material presented at past programs (from 1999 to 2014) may be accessed at *www.aasld.org.* Click on ''Events and Professional Development'' and then scroll down to ''Drug-Induced Liver Injury Conference.''

Dated: December 15, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2137]

Public Meeting on Patient-Focused Drug Development for Breast Cancer; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on patient-focused drug development for breast cancer. Patient-focused drug development is part of FDA's