

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
None .....	1,113,719	1	0.17	189,332.23

*Estimated Total Annual Burden Hours:* 189,332.23.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**  
*Reports Clearance Officer.*  
 [FR Doc. 2013-19058 Filed 8-6-13; 8:45 am]  
**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
 [Docket No. FDA-2012-N-0937]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Clinical Laboratory Improvement Amendments Waiver Applications**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Clinical Laboratory Improvement Amendments Waiver Applications" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On April 23, 2013, the Agency submitted a proposed collection of information entitled "Clinical Laboratory Improvement Amendments Waiver Applications" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0598. The approval expires on July 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: August 1, 2013.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
 [FR Doc. 2013-19053 Filed 8-6-13; 8:45 am]  
**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
 [Docket No. FDA-2012-D-1092]

**Minimizing Risk for Children's Toy Laser Products; Draft 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 draft guidance entitled "Minimizing Risk for Children's

Toy Laser Products." This draft guidance is to inform manufacturers of laser products, FDA headquarters and field personnel, and the public of the Center for Devices and Radiological Health's (CDRH) proposed approach on the safety of toy laser products. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 5, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Minimizing Risk for Children's Toy Laser Products" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft 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:** Robert J. Doyle, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4672, Silver Spring, MD 20993-0002, 301-796-5863.

**I. Background**

This draft guidance is to inform manufacturers of laser products, FDA headquarters and field personnel, and the public of CDRH's proposed approach 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. Although Federal law requires all laser products sold in the United States to 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 address children's toy laser products. FDA recently issued a proposed rule (78 FR 37723) that proposes to define children's toy laser products and require them to be within International Electrotechnical Commission (IEC) Class 1 emission limits. While this rulemaking process is ongoing, CDRH encourages manufacturers to keep children's toy laser products within IEC Class 1 emission limits in order to minimize the risk they pose to this vulnerable population.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's proposed approach on children's toys that are or that contain 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 draft guidance may do so by using the Internet. To receive "Minimizing Risk for Children's Toy Laser Products," you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1810 to identify the guidance you are requesting. 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>.

## IV. Paperwork Reduction Act of 1995

This draft guidance refers to a currently 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 21 CFR 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 regarding this document 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>.

Dated: August 1, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-19018 Filed 8-6-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0597]

#### Guidance for Industry on Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring." This guidance assists sponsors in developing risk-based monitoring strategies and plans for clinical investigations of human drugs, biologics, medical devices, and combinations thereof. The overarching goal of this guidance is to enhance human subject protection and the quality of clinical trial data by focusing sponsor oversight on the most important aspects of study conduct and reporting. The guidance makes clear that sponsors can use a variety of approaches to meet their responsibilities for monitoring investigational new drug or investigational device exemption studies.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002; the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448; or the Office of Communication and Education, Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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.

**FOR FURTHER INFORMATION CONTACT:** Ann Meeker-O'Connell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5356, Silver Spring, MD 20993-0002, 301-796-7615; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210; or Linda Godfrey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3446, Silver Spring, MD 20993-0002, 301-796-5490.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry entitled "Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring." FDA is publishing this guidance to assist sponsors of clinical investigations in developing risk-based monitoring strategies and plans for clinical investigations of human drug and biological products, medical devices, and combinations thereof. This guidance is intended to make clear that sponsors can use a variety of approaches to meet their responsibilities for monitoring clinical investigations under 21 CFR parts 312 and 812.