ANNUAL BURDEN ESTIMATES

<table>
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<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
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<tr>
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<td>1</td>
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<td>189,332.23</td>
</tr>
</tbody>
</table>

**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. 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 submitted within 60 days of this publication.

Robert Sargis,
Reports Clearance Officer.
[FR Doc. 2013–19053 Filed 8–6–13; 8:45 am]
BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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**

[FR 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**Minimizing Risk for Children’s Toy Laser Products: Draft Guidance for Industry and Food and Drug Administration Staff; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Minimizing Risk for Children’s Toy Laser Products.”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
confuse 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 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

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
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 guidance
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.

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.