We base our estimate of the average burden per response on our recent experience with the existing antimicrobial animal drug distribution reports program. We base our estimate of the number of affected respondents reported in tables 1 and 2 and the average number of responses per respondent in table 1 on a review of our records of sponsors with active and inactive applications. We estimate that 20 sponsors will have active applications, and we assume that half of the respondents will report electronically, while the other half will report on paper. We estimate that 10 sponsors with active applications will spend 62 hours annually to assemble the necessary information, prepare, and submit an annual antimicrobial animal drug sales and distribution report on paper, and 10 sponsors with active applications will spend 52 hours annually to assemble the necessary information, prepare, and electronically submit an annual antimicrobial animal drug sales and distribution report. We estimate that seven sponsors will have inactive applications, and we assume that half of these respondents will report electronically, while the other half will report on paper. We estimate that sponsors with inactive applications will spend 2 hours to prepare their annual antimicrobial animal drug sales and distribution reports, whether electronically or on paper.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping required by section 512(l)(3) of the FD&C Act	27	1	27	2	54

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Animal drug manufacturers are already required to maintain distribution records for their animal drug products to comply with FDA's current good manufacturing regulations for periodic drug reports under § 514.80(b)(4)(i) (21 CFR 514.80(b)(4)(i)), approved under OMB control number 0910–0284. Section 512(l)(3) of the FD&C Act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year. In addition, under 21 CFR 211.196 (approved under OMB control number 0910–0139), manufacturers currently are required to maintain distribution records that include dosage form and the date the drug is distributed. Based on these requirements, FDA believes that manufacturers already keep detailed records of the dates when antimicrobial drugs are distributed for marketing and recall purposes from which monthly reports can be prepared as part of usual and customary business practices. However, FDA estimates an additional recordkeeping burden of 54 hours for further compliance with section 512(l)(3) of the FD&C Act, as detailed in table 2.

Based on a review of the information collection since our last request for OMB approval, which was submitted with a final rule, we have made no adjustments to our burden estimates as reported in tables 1 and 2, other than to remove the one-time burden of 787 hours, which represented the time needed to review the provisions of the final rule and develop a compliance plan in the first year of compliance.

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09425 Filed 5–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2245]

Classification and Requirements for Laser Illuminated Projectors (Laser Notice No. 57); Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57).'' This guidance describes FDA's policy with respect to certain LIPs that comply with International Electrotechnical Commission (IEC) standards during laser product classification under the Electronic Product Radiation Control provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that apply to electronic products.

DATES: The announcement of the guidance is published in the **Federal Register** on May 8, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management

Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–2245 for ''Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57); Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 ''Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57)'' to the Office of Policy, 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.

FOR FURTHER INFORMATION CONTACT: Patrick Hintz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4228, Silver Spring, MD 20993–0002, 301–796–6927.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance describes FDA's policy with respect to certain LIPs that comply with IEC standards during laser product classification under the Electronic Product Radiation Control provisions of the FD&C Act (Pub. L. 90–602, amended by Pub. L. 103–80) that apply to electronic products. For purposes of this guidance, the term ''laser illuminated projector'' refers to a type of demonstration laser product regulated under 21 CFR 1040.10(b)(13) that is designed to project a display image without the use of raster-scanned collimated laser beams. LIPs may be used in locations such as indoor or outdoor cinema theaters, laser shows, presentations at conventions, image/data projectors in office settings, or homes. Under 21 CFR 1040.10(c), FDA recognizes four major hazard classes (I to IV) of lasers, including three subclasses (IIa, IIIa, and IIIb). Under this classification procedure higher laser classes correspond to more powerful lasers and a higher potential to pose serious danger if used improperly.

As demonstration laser products, LIPs and applications for LIPs cannot exceed class IIIa emission limits as specified in 21 CFR 1040.11(c) (which is comparable to IEC 60825–1 Ed. 3.0 Class 3R) unless granted a variance by FDA under 21 CFR 1010.4. Some LIPs and applications for LIPs will exceed the class IIIa limits and therefore require a variance to exceed those emission limits.

This guidance document describes FDA's intent to clarify the application of certain aspects of the performance standard requirements in 21 CFR 1040.11(c) for LIPs. Because the radiant emission levels produced by LIPs can be scientifically characterized by an alternative IEC standard, IEC 62471–5:Ed. 1.0, FDA does not intend to enforce the requirements under 21 CFR 1040.10(c)(1) and 21 CFR 1040.11(c) when LIP manufacturers conform to these standards under the situations outlined in sections III and IV of this guidance.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of October 2, 2017 (82 FR 45861). FDA revised the guidance as appropriate in response to the comments. This guidance supersedes ''Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors (LIPs); Guidance for Industry and Food and Drug Administration Staff,'' issued February 18, 2015.

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 current thinking of FDA on classification and requirements for LIPs (Laser Notice No. 57). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

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 Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400056 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are 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 collections

of information in the following FDA regulations and forms have been approved by OMB as listed in the following table:

21 CFR part and form	Topic	OMB control No.
1002, 1010, 1040, and form FDA 3632 ...	Reporting and Recordkeeping for Electronic Products—General Requirements	0910–0025

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09380 Filed 5–7–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2049]

Medical X-Ray Imaging Devices Conformance With International Electrotechnical Commission Standards; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Medical X-Ray Imaging Devices Conformance with IEC Standards.'' This guidance describes FDA's policy regarding the regulation of medical x-ray imaging equipment that is subject to the Federal Food, Drug and Cosmetic Act (FD&C Act) and FDA's regulations that apply to medical devices and electronic products.

DATES: The announcement of the guidance is published in the **Federal Register** on May 8, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–2049 for ''Medical X-Ray Imaging Devices Conformance with IEC Standards.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 ''Medical X-Ray Imaging Devices Conformance with IEC Standards'' to the Office of Policy, 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.

FOR FURTHER INFORMATION CONTACT: Robert Sauer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5628, Silver Spring, MD 20993–0002, 301–796–3580.

SUPPLEMENTARY INFORMATION: