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Classification and Requirements for Laser Illuminated Projectors (Laser Notice No. 57); Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57); Draft Guidance for Industry and Food and Drug Administration Staff." When finalized, 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 (the FD&C Act) that apply to electronic products. When finalized, this document will supersede the "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. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic submissions as follows:

- 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); Draft 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.fda.gov/regulatoryinformation/dockets/default.htm.

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 draft guidance document entitled "Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57); Draft Guidance for Industry and Food and Drug Administration Staff" 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.

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

When finalized, this guidance describes FDA's policy with respect to certain laser illuminated projectors 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" (LIP) refers to a type of demonstration laser product regulated under 21 CFR 1040.10(b)(13) that is designed to project full-frame digital images. LIPs may be used in locations such as indoor or outdoor cinema theaters, laser shows, presentations at conventions, as image/data projectors in an office setting, or in a home.

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. 2.0 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 62471-5:2015, FDA does not intend to consider whether LIP manufacturers that conform to these standards under the situations outlined in sections III and IV of this

guidance also comply with 21 CFR 1040.10(c)(1) and 21 CFR 1040.11(c). For LIP manufacturers who choose not to conform to these standards under the situations outlined in sections III and IV of this guidance, such manufacturers should evaluate these laser products in accordance with FDA's guidance entitled "Laser Products--Conformance with IEC 60825-1 and IEC 60601-2-22 (Laser Notice No. 50); Guidance for Industry and FDA Staff" (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094361.htm) or must continue to comply with 21 CFR 1040.10(c) and 21 CFR 1040.11(c), among other applicable requirements.

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, when finalized, will represent the current thinking of FDA on classification and requirements for laser illuminated projectors. 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 draft 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. Guidance documents are also available at https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm or https://www.regulations.gov. Persons unable to download an electronic copy of

"Classification and Requirements for Laser Illuminated Projectors (Laser Notice No. 57); Draft Guidance for Industry and Food and Drug Administration Staff" 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 found in FDA regulations. 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 21 CFR parts 1002, 1010, and 1040 are approved under OMB control number 0910-0025.

Dated: September 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-21079 Filed: 9/29/2017 8:45 am; Publication Date: 10/2/2017]