



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-2245]

Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors; 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 “Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors (LIPs).” 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.

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, submit either electronic or written comments on the guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 “Immediately in Effect Guidance Document: Classification and Requirements for Laser

Illuminated Projectors” 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: Patrick Hintz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4248, Silver Spring, MD 20993-0002, 301-796-6927.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled “Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors.” This guidance is being issued consistent with FDA’s good guidance practices (GGPs) regulation (21 CFR 10.115). The guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). The Agency made this determination because the guidance presents a less burdensome policy consistent with the public health. Although this guidance is immediately in effect, it remains subject to comment in accordance with the Agency’s GGPs regulation. 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 that apply to electronic products. The regulations for classifying laser products are set forth in part 1040 (21 CFR part 1040).

For purposes of this guidance, the term “laser illuminated projector” refers to a type of demonstration laser product regulated under § 1040.10(b)(13) that is designed to project full-frame digital images. The term “demonstration laser product” is defined under § 1040.10(b)(13) to mean, “Any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition.” 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.

Lasers are being used in LIPs as an alternative to conventional lamps in projectors. Although these LIPs emit laser light from extended sources and their uncollimated beams do not present the same hazards as other lasers, they are laser products that present risks and must undergo classification in accordance with § 1040.10(c).

Under § 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 the potential to pose serious danger if used improperly.

As demonstration laser products, LIPs cannot exceed class IIIa (which is comparable to IEC class 3R) emissions limits as specified in § 1040.11(c) unless granted a variance by FDA under § 1010.4. Many 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 with regard to the application of certain aspects of the performance standard requirements in § 1040.11(c) for LIPs. The IEC standards

used to evaluate lamps are applicable to characterizing ocular hazards in LIPs, because a laser retinal hazard is related to the radiance of the laser source and the radiant emission levels produced by LIPs are comparable to conventional lamps. Because the radiant emission levels produced by LIPs can scientifically be characterized by an alternative IEC standard, FDA does not intend to consider whether LIP manufacturers that conform to these standards under the situations described in this guidance also comply with §§ 1040.10(c) and 1040.11(c).

II. Significance of Guidance

The guidance represents the Agency's current thinking on the classifications and requirements for LIPs. 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 Center for Devices and Radiological Health 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 "Immediately in Effect Guidance Document: Classification and Requirements for Laser Illuminated Projectors" 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 (the PRA) (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.

The labeling referenced in section (IV)(c)(ii) of the guidance does not constitute a “collection of information” under the PRA because the labeling is a “public disclosure of information supplied by the Federal Government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

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>.

Dated: February 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-03209 Filed 02/17/2015 at 8:45 am; Publication Date: 02/18/2015]