

countermeasure priority review voucher user fees authorized by 21 U.S.C. 360bbb–4a, shall be credited to this account, to remain available until expended.” (Pub. L. 115–31, Division A, Title VI).

The material threat MCM priority review fee established in the new fee schedule must be paid for any application that is received on or after October 1, 2017, and submitted with a priority review voucher. This fee must be paid in addition to any other fee due under PDUFA. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, credit card, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. (NOTE: only full payments are accepted. No partial payments can be made online.) Once you search for your invoice, select “Pay Now” to be redirected to *Pay.gov*. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA Web site after the user fee ID number is generated.

If paying with a paper check the user fee identification (ID) number should be included on the check, followed by the words “Material Threat Medical Countermeasure Priority Review.” All paper checks must be in U.S. currency from a U.S. bank made payable and mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (NOTE: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). The FDA post office box number (P.O. Box 979107) must be written on the check. If needed, FDA’s

tax identification number is 53–0196965.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. The account information is as follows: U.S. Dept. of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Number: 75060099, Routing Number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002.

#### V. Reference

The following reference is on display in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Ridley, D.B., H.G. Grabowski, and J.L. Moe, “Developing Drugs for Developing Countries,” *Health Affairs*, vol. 25, no. 2, pp. 313–324, 2006.

Dated: September 28, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–21191 Filed 9–29–17; 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); 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 December 1, 2017 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](mailto: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 9–29–17; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. FDA–2017–N–5442]

**Leveraging Quantitative Methods and  
Modeling To Modernize Generic Drug  
Development and Review; Public  
Workshop; Request for Comments**

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

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled “Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review.” The purpose of the public workshop is to engage stakeholders in a discussion of current and emerging scientific approaches and applications for the conduct of quantitative modeling and simulations in generic drug development, especially for complex and locally acting products, and to gain input regarding opportunities and knowledge gaps related to the use of quantitative modeling and simulation to inform regulatory decision making through the product lifecycle. FDA will use the information gained through the workshop to support product-specific guidance development, improve pre-abbreviated new drug applications (ANDA) interactions with applicants, increase the quality and efficiency of regulatory reviews, and identify a next generation modeling and simulation toolset for complex and locally acting products.

**DATES:** The public workshop will be held on October 2 and 3, 2017, from 8:30 a.m. to 4:30 p.m. Submit either electronic or written comments on this

public workshop by November 3, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Great Room, Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 3, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of November 3, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

**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–2017–N–5442 for “Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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