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**FOR FURTHER INFORMATION CONTACT:** Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1115, Silver Spring, MD 20993-0002, 301-796-5333, email: [CDERDataStandards@fda.hhs.gov](mailto:CDERDataStandards@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On December 17, 2014, FDA published final guidance for industry "Providing Regulatory Submissions in Electronic Format—Standardized Study Data" (eStudy Data) posted on FDA's Study Data Standards Resources Web page at <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>. The eStudy Data guidance implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k-1(a)) for study data contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) to the Center for Biologics Evaluation and Research (CBER) or CDER by specifying the format for electronic submissions. The implementation of electronic submission requirements for study data became effective on December 17, 2016 (24 months after issuance of final guidance for NDAs, BLAs, ANDAs, and 36 months for INDs). The eStudy Data guidance states that a **Federal Register** notice will specify the transition date for all version updates (with the month and day for the transition date corresponding to March 15).

The transition date for support of version 1.1 of ADaM IG V 1.1 is March 15, 2018. ADaM IG V.1.1 is supported as of this **Federal Register** notice and sponsors or applicants are encouraged to begin using it, the new version will only be required in submissions for studies that start after March 15, 2019. The Catalog will list March 15, 2019, which will be reflected in the Catalog, as the "date requirement begins." When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select any of those version to use.

The transition date for the end of FDA support for ADaM IG V 1.0, is March 15, 2018.

##### II. Electronic Access

Persons with access to the Internet may obtain the referenced material at <http://www.fda.gov/ectd>.

Dated: September 22, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-21081 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-0007]

##### Fee for Using a Material Threat Medical Countermeasure Priority Review Voucher in Fiscal Year 2018

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the fee rate for using a material threat medical countermeasure (MCM) priority review voucher for fiscal year (FY) 2018. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to determine and collect material threat MCM priority review user fees for certain applications for review of human drug products when those applications use a material threat MCM priority review voucher. These vouchers are awarded to the sponsors of material threat MCM applications that meet all of the requirements of this program upon FDA approval of such applications. The amount of the fee for using a material threat MCM priority review voucher is determined each FY based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous FY, and the average cost incurred in the review of an application that is not subject to priority review in the previous FY. This notice establishes the material threat MCM priority review fee rate for FY 2018 and outlines the payment procedures for such fees.

**FOR FURTHER INFORMATION CONTACT:**

Robert J. Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14202F, Silver Spring, MD 20993-0002, 301-796-7223.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 3086 of the Cures Act (Pub. L. 114-255) added section 565A to the FD&C Act (21 U.S.C. 360bbb-4a). In section 565A of the FD&C Act, Congress encouraged development of material threat MCMs by offering additional incentives for obtaining FDA approval of such products. Under section 565A of the FD&C Act, the sponsor of an eligible material threat MCM application (as defined in section 565A(a)(4)) shall receive a priority review voucher upon approval of the material threat MCM application. The recipient of a material threat MCM priority review voucher may either use the voucher for a future human drug application submitted to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or transfer (including by sale) the voucher to another party. The voucher may be transferred (including by sale) repeatedly until it ultimately is used for a human drug application submitted to FDA under section 505(b)(1) of the FD&C Act or section 351(a) of the Public Health Service Act. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months after the receipt or filing date, depending on the type of application. Information regarding PDUFA goals is available at <https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf>.

The applicant that uses a material threat MCM priority review voucher is entitled to a priority review of its eligible human drug application, but must pay FDA a material threat MCM priority review user fee in addition to any user fee required by PDUFA for the application. Information regarding the material threat MCM priority review voucher program is available at: <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm566498.htm#prv>.

This notice establishes the material threat MCM priority review fee rate for FY 2018 at \$2,830,579 and outlines FDA's procedures for payment of material threat MCM priority review user fees. This rate is effective on October 1, 2017, and will remain in effect through September 30, 2018.

**II. Material Threat Medical Countermeasure Priority Review User Fee for FY 2018**

FDA interprets section 565A(c)(2) of the FD&C Act as requiring that FDA determine the amount of the material threat MCM priority review user fee each fiscal year based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous fiscal year, and the average cost incurred by FDA in the review of a human drug application that is not subject to priority review in the previous fiscal year.

A priority review is a review conducted with a PDUFA goal date of 6 months after the receipt or filing date, depending on the type of application. Under the PDUFA goals letter, FDA has committed to reviewing and acting on 90 percent of the applications granted priority review status within this expedited timeframe. Normally, an application for a human drug product will qualify for priority review if the product is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. An application that does not receive a priority designation will receive a standard review. Under the PDUFA goals letter, FDA has committed to reviewing and acting on 90 percent of standard applications within 10 months of the receipt or filing date, depending on the type of application. A priority review involves a more intensive level of effort and a higher level of resources than a standard review.

As interpreted by FDA, section 565A of the FD&C Act requires that the fee amount should be based on the difference between the average cost incurred by the Agency in the review of a human drug application subject to a priority review in the previous fiscal year, and the average cost incurred by the Agency in the review of a human drug application not subject to a priority

review in the previous fiscal year. FDA is setting a fee for FY 2018, which is to be based on standard cost data from the previous fiscal year, FY 2017. However, the FY 2017 submission cohort has not been closed out yet, thus the cost data for FY 2017 are not complete. The latest year for which FDA has complete cost data is FY 2016. Furthermore, because FDA has never tracked the cost of reviewing applications that get priority review as a separate cost subset, FDA estimated this cost based on other data that the Agency has tracked. FDA uses data that the Agency estimates and publishes on its Web site each year—standard costs for review. FDA does not publish a standard cost for “the review of a human drug application subject to priority review in the previous fiscal year.” However, we expect all such applications would contain clinical data. The standard cost application categories with clinical data that FDA publishes each year are: (1) New drug applications (NDAs) for a new molecular entity (NME) with clinical data and (2) biologics license applications (BLAs).

The standard cost worksheets for FY 2016 show standard costs (rounded to the nearest hundred dollars) of \$5,929,100 for an NME NDA, and \$4,887,100 for a BLA. Based on these standard costs, the total cost to review the 49 applications in these two categories in FY 2016 (27 NME NDAs with clinical data and 22 BLAs) was \$267,601,900. (NOTE: These numbers exclude the President’s Emergency Plan for AIDS Relief NDAs; no investigational new drug review costs are included in this amount.) Twenty-three of these applications (14 NDAs and 9 BLAs) received priority review, which would mean that the remaining 26 received standard reviews. Because a priority review compresses a review schedule that ordinarily takes 10 months into 6 months, FDA estimates that a multiplier of 1.67 (10 months divided by 6 months) should be applied to non-priority review costs in

estimating the effort and cost of a priority review as compared to a standard review. This multiplier is consistent with published research on this subject that supports a priority review multiplier in the range of 1.48 to 2.35 (Ref. 1). Using FY 2016 figures, the costs of a priority and standard review are estimated using the following formula:

$$(23 \alpha \times 1.67) + (26 \alpha) = \$267,601,900$$

Where “α” is the cost of a standard review and “α times 1.67” is the cost of a priority review.

Using this formula, the cost of a standard review for NME NDAs and BLAs is calculated to be \$4,154,664 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or \$6,938,289 (rounded to the nearest dollar). The difference between these two cost estimates, or \$2,783,625, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2018 fee, FDA will need to adjust the FY 2016 incremental cost by the average amount by which FDA’s average costs increased in the 3 years prior to FY 2017, to adjust the FY 2016 amount for cost increases in FY 2017. That adjustment, published in the **Federal Register** on September 14, 2017 (see 82 FR 43244 at 43245), setting FY 2018 PDUFA fees, is 1.6868 percent for the most recent year, not compounded. Increasing the FY 2016 incremental priority review cost of \$2,783,625 by 1.6868 percent (or 0.016868) results in an estimated cost of \$2,830,579 (rounded to the nearest dollar). This is the material threat MCM priority review user fee amount for FY 2018 that must be submitted with a priority review voucher for a human drug application in FY 2018, in addition to any PDUFA fee that is required for such an application.

**III. Fee Schedule for FY 2018**

The fee rate for FY 2018 is set out in table 1:

TABLE 1—MATERIAL THREAT MEDICAL COUNTERMEASURE PRIORITY REVIEW SCHEDULE FOR FY 2018

Fee category	Fee rate for FY 2018
Application submitted with a material threat MCM priority review voucher in addition to the normal PDUFA fee .....	\$2,830,579

**IV. Implementation of Material Threat Medical Countermeasure Priority Review User Fee**

Under section 565A(c)(4)(A) of the FD&C Act, the priority review user fee is due upon submission of a human

drug application for which the priority review voucher is used. Section 565A(c)(4)(B) of the FD&C Act specifies that the application will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA

payment procedures. In addition, section 565A(c)(4)(C) specifies that FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act. FDA’s appropriation for FY 2018, states specifically that “medical

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.”