

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.

**FOR FURTHER INFORMATION CONTACT:** Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: [kalyani.bhatt@fda.hhs.gov](mailto:kalyani.bhatt@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at <https://www.fda.gov/Advisory-Committees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** The committees will discuss the efficacy, safety, and benefit-risk profile of new drug application (NDA) 211371, brexanolone 5 mg/mL intravenous injection, submitted by Sage Therapeutics, for the proposed indication of postpartum depression.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** Interested persons may present data, information, or views,

orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 18, 2018, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 10, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 11, 2018.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require special accommodations due to a disability, please contact Kalyani Bhatt (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 20, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-0007]

### Fee for Using a Material Threat Medical Countermeasure Priority Review Voucher in Fiscal Year 2019

**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) 2019. 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 applicants 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 to review of a human drug application designated as 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 2019 and outlines the payment procedures for such fees.

**FOR FURTHER INFORMATION CONTACT:** Lola Olajide, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14541B, Silver Spring, MD 20993-0002, 240-402-4244.

**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 applicant 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>.

This notice establishes the material threat MCM priority review fee rate for FY 2019 at \$2,457,140 and outlines FDA's procedures for payment of material threat MCM priority review user fees. This rate is effective on October 1, 2018, and will remain in effect through September 30, 2019.

## II. Material Threat Medical Countermeasure Priority Review User Fee for FY 2019

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 receives 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 2019, which is to be based on standard cost data from the previous fiscal year, FY 2018. However, the FY 2018 submission cohort has not been closed out yet, thus the cost data for FY 2018 are not complete. The latest year for which FDA has complete cost data is FY 2017. 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 website 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 2017 show standard costs of \$5,340,560 for an NME NDA, and \$4,596,936 for a BLA. Based on these standard costs, the total cost to review the 57 applications in these two categories in FY 2017 (31

NME NDAs with clinical data and 26 BLAs) was \$285,077,688. (*Note:* These numbers exclude the President's Emergency Plan for AIDS Relief NDAs; no investigational new drug review costs are included in this amount.) Thirty-three of these applications (20 NDAs and 13 BLAs) received priority review, which would mean that the remaining 24 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 ÷ 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 2017 figures, the costs of a priority and standard review are estimated using the following formula:

$$(33 \alpha \times 1.67) + (24\alpha) = \$285,077,688$$

where “ $\alpha$ ” is the cost of a standard review and “ $\alpha$  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 \$3,603,561 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or \$6,017,946 (rounded to the nearest dollar). The difference between these two cost estimates, or \$2,414,386, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2019 fee, FDA will need to adjust the FY 2017 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2018, to adjust the FY 2017 amount for cost increases in FY 2018. That adjustment, published in the **Federal Register** on August 1, 2018 (see 83 FR 37504), setting FY 2019 PDUFA fees, is 1.7708 percent for the most recent year, not compounded. Increasing the FY 2017 incremental priority review cost of \$2,414,386 by 1.7708 percent (or 0.017708) results in an estimated cost of \$2,457,140 (rounded to the nearest dollar). This is the material threat MCM priority review user fee amount for FY 2019 that must be submitted with a priority review voucher for a human drug application in FY 2019, in addition to any PDUFA fee that is required for such an application.

## III. Fee Schedule for FY 2019

The fee rate for FY 2019 is set out in table 1:

TABLE 1—MATERIAL THREAT MEDICAL COUNTERMEASURE PRIORITY REVIEW SCHEDULE FOR FY 2019

Fee category	Fee rate for FY 2019
Application submitted with a material threat MCM priority review voucher in addition to the normal PDUFA fee .....	\$2,457,140

#### 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.

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, 2018, 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 <https://www.pay.gov/public/home>. 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 website 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.

#### V. Reference

The following reference is on display at 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; it is not available electronically at <https://www.regulations.gov> as this reference is copyright protected. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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, available at: [https://faculty.fuqua.duke.edu/~willm/HSM\\_](https://faculty.fuqua.duke.edu/~willm/HSM_)

*RA/Documents/HA2006\_Ridley\_Vouchers.pdf*.

Dated: September 20, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2014-D-2138]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by October 26, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0800. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA