

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.

- 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_

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 aira_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, PRStaff@fda.hhs.gov.

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

has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910-0800—Extension

This information collection supports Agency implementation of the Drug Quality and Security Act (Pub. L. 113-54), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding new section 503B (21 U.S.C. 353b). Under section 503B(b) of the FD&C Act, a compounder can register as an outsourcing facility with FDA. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug

applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

Under section 503B(b)(5) of the FD&C Act, an outsourcing facility must submit adverse event reports to FDA in accordance with the content and format requirements established through guidance or regulation under § 310.305 (21 CFR 310.305) (or any successor regulations). Accordingly, we developed the document, “Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.” For a copy of guidance documents, go to <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>, insert the title of the guidance document in the “Search” box and follow the prompts. The guidance explains electronic reporting of adverse events in accordance with § 310.305 with respect to outsourcing facilities.

Under § 310.305(c)(1), manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved NDA or ANDA, including, as set forth in the

guidance, outsourcing facilities must submit to FDA adverse event reports within 15 calendar days of receiving the information and must submit follow-up reports within 15 calendar days of receipt of new information about the adverse event, or as requested by FDA. Outsourcing facilities must submit the adverse event report in an electronic format that FDA can process, review, and archive (collection of information is approved by OMB control number 0910-0291). A copy of the current labeling of the compounded drug product must be provided.

Under § 310.305(f), entities subject to the regulation must maintain for 10 years the records of all adverse events required to be reported under § 310.305. The outsourcing facility should also maintain records of its efforts to obtain the data elements described in the draft guidance for each adverse event report.

In the **Federal Register** of August 21, 2018 (83 FR 28854), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden for the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| Compounding outsourcing facility | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Submission of adverse event reports' including copy of labeling and other information as described in the guidance | 55 | 1 | 55 | 1.1 | 61 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

| Type of recordkeeping | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|-------------------------|------------------------------------|----------------------|----------------------------------|-------------|
| Records of adverse events, including records of efforts to obtain the data elements for each adverse event report | 55 | 1 | 55 | 16 | 880 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

This is the first extension of the information collection and we have retained the currently approved burden estimate. Based on our review of Agency data, we estimate that annually 55 outsourcing facilities (“Number of Respondents” and “Total Annual Responses” in table 1) will submit adverse event reports to FDA as specified in the guidance and that preparing and submitting this information will take approximately 1.1 hours per registrant (“Average Burden per Response” in table 1). Likewise, we

estimate that annually 55 outsourcing facilities (“Number of Recordkeepers” in table 2) will maintain records of adverse events as specified in the guidance and that preparing and maintaining the records will take approximately 16 hours per registrant (“Average Burden per Recordkeeping” in table 2).

Dated: September 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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