submission date. See sections 524(b)(4), 529(b)(4)(B), and 565A(b)(3)(A) of the FD&C Act.

*B. Priority Review Voucher User Fee Due Date*

Under sections 524(c)(4)(A) (tropical disease priority review user fee) and 565A(c)(4)(A) (material threat MCM priority review user fee) of the FD&C Act, the priority review user fee is due (*i.e.,* the obligation to pay the fee is incurred) upon submission of a human drug application for which the priority review voucher is used.[4]

Under section 529(c)(4)(A) (rare pediatric disease priority review user fee) of the FD&C Act, the priority review user fee is due (*i.e.,* the obligation to pay the fee is incurred) when a sponsor notifies FDA of its intent to use the voucher. Upon receipt of this notification, FDA will issue an invoice to the sponsor for the rare pediatric disease priority review voucher fee. The invoice will include instructions on how to pay the fee via wire transfer, check, or online payments.

## V. Fee Payment Options and Procedures

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 website after the user fee identification (ID) number is generated.

*A. Paper Check Payment Process*

If paying by paper check, the sponsor should include on the check the appropriate reference number and the type of review requested. For rare pediatric disease priority review, please use the invoice number issued by the FDA. The invoice number is issued by the FDA upon receipt of the rare pediatric priority review notification (see section IV.A). For tropical disease priority review and for material threat MCM priority review, please use the user fee ID number generated for the *Pay.gov* feature.

- Tropical disease priority review: A paper check for a tropical disease priority review fee should include the user fee ID number and the words: ''Tropical Disease Priority Review''.
- Rare pediatric disease priority review: A paper check for a rare pediatric disease priority review fee should include the invoice number followed by the words: ''Rare Pediatric Disease Priority Review''.
- Material threat MCM priority review: A paper check for a material threat MCM priority review fee should include the user fee ID number and the words: ''Material Threat Medical Countermeasure Priority Review'' (or ''MCMPRV'').

All paper checks should 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.

*B. Wire Transfer Payment Process*

If paying by wire transfer, please reference your invoice number/unique user fee ID number when completing your transfer. (For rare pediatric priority review, please use your invoice number issued by the FDA upon receipt of notification. For all other priority reviews, please use the unique user fee ID number generated for the *Pay.gov* feature.) 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 the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Number: 75060099, Routing Number: 021030004, SWIFT: FRNYUS33.

## VI. Reference

The following reference is on display with the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD, 20852, 240–402–7500, 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://www.healthaffairs.org/doi/full/10.1377/hlthaff.25.2.313.*

Dated: October 4, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–21969 Filed 10–5–22; 11:15 am]

**BILLING CODE 4164–01–P**

[4] In the case of ''rolling review'' of an application (as discussed in May 2014 ''expedited programs'' guidance) for which a tropical disease PRV or material threat MCM PRV is redeemed, the PRV fee is due upon submission of the final portion of the application, given that the Agency generally views ''submission of a human drug application'' (including as used in sections 524(c)(4)(A) and 565A(c)(4)(A)) to mean the submission of a complete application. Also see section 506(d) of the FD&C Act, relating to review of incomplete applications for approval of a fast track product.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–0030]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Drug Compounding Under Sections 503A and 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:** Submit written comments (including recommendations) on the collection of information by November 7, 2022.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 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, *PRAStaff@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.

**Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act**

**OMB Control Number 0910–0800—Revision**

This information collection helps support implementation of sections 503A (21 U.S.C. 353a) and 503B (21 U.S.C. 353b) of the Federal Food Drug and Cosmetic Act (FD&C Act), which govern requirements for pharmacy compounding and outsourcing facilities, respectively. For efficiency of Agency operations, we are revising the information collection to include related reporting activities currently approved under OMB control number 0910–0827. Specifically, upon electing and in order to become an outsourcing facility, respondents must register under section 503B of the FD&C Act and submit certain reports and updates to FDA. The information is required to be submitted by electronic means unless otherwise exempt, and prepared in such form and manner as the Secretary of the Department of Health and Human Services may prescribe through regulation or guidance.

In the guidance for industry entitled ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' (December 2016), available on our website at *https://www.fda.gov/media/90173/download,* we explain how facilities that elect to register with FDA as outsourcing facilities are to submit drug product reports, consistent with section 503B of the FD&C Act. The guidance document describes who must report and what information must be provided to FDA. The guidance document also explains that drug compounding reports must be submitted in structured product labeling (SPL) format using FDA's electronic submissions system and discusses the consequences of outsourcing facilities' failure to submit reports.

In the **Federal Register** of June 17, 2022 (87 FR 36507) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Section 503B of the FD&C Act | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Initial product reports | 3 | 53 | 159 | 0.0833 (5 minutes) | 13.25 |
| Waiver request from electronic submission of initial product reports. | 1 | 1 | 1 | 1 | 1 |
| June product reports | 75 | 53 | 3,975 | 0.025 (1.5 minutes) | 99.375 |
| December product reports | 75 | 53 | 3,975 | 0.025 (1.5 minutes) | 99.375 |
| Waiver request from electronic submission of product reports. | 1 | 1 | 1 | 1 | 1 |
| Total | | | | | 214 |

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

Respondents to this collection of information are outsourcing facilities. Based upon our evaluation of the information collection, we have adjusted our estimate downward by 16 hours (from 230 to 214) annually to reflect more recent Agency data. We estimate that each year three outsourcing facilities will submit a product report upon initial registration under section 503B of the FD&C Act. We estimate that twice each year 75 outsourcing facilities will submit a report identifying all human drugs compounded in the facility in the previous 6 months. For the purposes of this estimate, each product's SPL submission is considered a separate product response, and therefore each facility's product report will include multiple product responses. We estimate that each facility will average 53 product responses. We expect each product report will consist of multiple product responses per facility and estimate that preparing and submitting this information electronically may take up to 5 minutes for each initial product response.

Assuming an average of 53 product responses per facility, we estimate that, for semiannual reports, preparing and submitting this information electronically will take 1.5 minutes per product response. Our burden estimate for semiannual product report submissions is lower than for initial product reports because outsourcing facilities can save each product response once initially created and submitted. For subsequent reports, an outsourcing facility may resubmit the same file(s) after changing the RootID and version number (both SPL metadata), effective date (to identify the reporting period), and the number of units produced, along with other data as appropriate, to appropriate values for the reporting period. Furthermore, if a product was not compounded during a particular reporting period, no product response would be sent for that product during that reporting period.

We expect to receive no more than one waiver request from the electronic submission process for initial product reports and semiannual reports, and that each waiver request will take 60 minutes to prepare and submit.

Dated: September 30, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–21841 Filed 10–6–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–2389]**

### Authorization of Emergency Use of a Biological Product in Response to an Outbreak of Monkeypox; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of monkeypox. FDA has issued one Authorization for a biological product as requested by the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health. The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of the Department of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States (U.S.) citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on August 9, 2022, that circumstances exist justifying the authorization of emergency use of vaccines pursuant to the FD&C Act, subject to the terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

**DATES:** The Authorization is effective as of August 9, 2022.

**ADDRESSES:** Submit written requests for a single copy of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

**FOR FURTHER INFORMATION CONTACT:** Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

## II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, and 360e) or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.