UNITED STATES FOOD & DRUG ADMINISTRATION

Tropical Disease Priority Review Vouchers

OMB Control No. 0910-0822 – EXTENSION

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of Food and Drug Administration (FDA) guidance. Section 1102 of the Food and Drug Administration Amendments Act (FDAAA) added section 524 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to encourage development of new drug or biological products for the prevention or treatment of certain tropical diseases affecting millions of people throughout the world. Section 524 makes provisions for awarding a priority review voucher (PRV) to sponsors of product applications for the prevention or treatment of certain tropical diseases. Section 524 of the FD&C Act serves to stimulate new drug development for drugs to prevent or treat a "*tropical disease*" (as defined in section 524(a)(3)) by offering additional incentives for obtaining FDA approval for pharmaceutical treatments for these diseases. Under section 524 of the FD&C Act, a sponsor of a "*tropical disease product application*," as defined in section 524(a)(4), may be eligible for a voucher that can be used to obtain a priority review for any other application submitted under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (PHS Act).

Accordingly, we have developed the procedural guidance document entitled "*Tropical Disease Priority Review Vouchers"* (October 2016), available for download from our website at https://www.fda.gov/media/72569/download). The guidance document explains how FDA implements provisions of section 524 of the FD&C Act and how sponsors may qualify for a tropical disease PRV based on eligibility criteria set forth in the statute, how to use PRVs, and how PRVs may be transferred to other sponsors. The guidance document also communicates that section 524 requires attestation by the sponsor of eligibility for a PRV upon submission of the marketing application.

We therefore request approval of the information collection provisions established in section 524 of the FD&C Act, as discussed and implemented in the associated agency guidance.

2. Purpose and Use of the Information Collection

Description of Respondents: Sponsors submitting certain eligible tropical disease product applications under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

The PRV program enables sponsors of certain FDA-regulated tropical disease product applications to seek expedited or priority review of applications submitted in accordance

with the statute.

3. Use of Improved Information Technology and Burden Reduction

To assist respondents with requests for PRVs, we have provided procedural agency guidance. Information is submitted electronically in conjunction with drug product marketing applications. Our guidance documents, along with other resources available from our website, are intended to assist with all application-related submissions.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

FDA believes the information collection poses no undue burden on small entities. Rather, it provides a pathway for sponsors of certain products to request expedited FDA review. In addition, we provide assistance to respondents of the information collection through resources available from our website, along with small business assistant staffs throughout the agency.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory requirements. Section 524 of the FD&C Act authorizes FDA to award PRVs to sponsors of certain tropical disease product applications that meet the specified statutory criteria. Additionally, review and approval of safety and effectiveness of human drug applications establishes a reporting frequency that is dictated by the need to focus on potential problems concerning the safety and effectiveness of human drugs. Less frequent data collection would hinder the incentives offered under the PRV program.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the *Federal Register* of May 1, 2025, (90 FR 18680), FDA published a 60-day notice requesting public comment on the proposed collection of information. Comments were posted to the docket (FDA-2025-N-0418), as detailed below, which were summarized in our 30-day *Federal Register* notice of July 29, 2025 (90 FR 35684):

> (Comment 1) Communicated general support for the proposed collection of information, noting that the PRV program can help incentivize investment and development of treatments for tropical diseases. One comment also noted that the information collected can help ensure transparency, accountability, and proper

administration of the PRV program.

(Response 1) We agree that the information being collected has utility and can help ensure transparency, accountability, and administration of the tropical disease PRV program.

(Comment 2) One comment noted that the estimated annual burden appeared reasonable given the limited number of PRVs issued each year. Another comment supported FDA's efforts to streamline the administrative burden of the tropical disease PRV program. One comment recommended that FDA continue to monitor the administrative burden, especially for first-time applicants, and consider providing templates, guidance, and case studies to help streamline submissions.

(Response 2) We appreciate the commenter's support of FDA's efforts to streamline the administrative burden of the PRV program and agree will consider developing templates, additional guidance, or case studies to help streamline submissions as our limited resources will allow.

(Comment 3) One comment included recommendations for FDA toward enhancing digital submission portals, automated acknowledgement systems for PRV transfers and redemption, and integration of PRV-related submissions with existing regulatory submission platforms.

(Response 3) We appreciate and will consider these recommendations, intending continued enhancements to submission mechanisms as our limited resources will allow.

We made no adjustment to our burden estimate as a result of the public comments.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is provided to respondents to the information collection. However, the tropical disease PRV program provides an incentive for development of treatments for specified tropical diseases in the form of an award of a PRV upon approval of the tropical disease product application for use when submitting another future marketing application (not necessarily for a tropical disease indication).

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted may include *point of contact name*, *email address*, *phone number*, *fax number*, and *mailing address*. We have determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other

requirements of the Privacy Act do not apply. Specifically, neither the contractor nor FDA uses *name* or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, and their property rights in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature associated with the information collection.

12. Estimates of Annualized Burden Hours and Cost

12a. Estimated Annual Hourly Burden.

Table 1--Estimated Annual Reporting Burden[1]

Reporting Under Section 524 of the FD&C Act	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Priority Review Voucher Request	1	1	1	8	8
Notifications of Intent To Use a Voucher	2	1	2	8	16
Letters Indicating the Transfer of a Voucher Letter	1	1	1	8	8
Acknowledging the Receipt of a Transferred Voucher	1	1	1	8	8
Attestation of Eligibility	1	1	1	2	2
Total					42

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

During the last 3 years, we have not received any new Priority Review Voucher requests or Attestations of eligibility; therefore, we estimate we will receive one or fewer of each of these submissions annually. Although we have not received any of these submissions in the last 3 years, these information collection provisions should be extended to provide for the potential future need of respondents to submit them.

12b. Annualized Cost Burden Estimate.

We assume an average pharmaceutical industry wage rate of $85.00 per hour for preparing and submitting the information collection under the guidance. We calculate the total hours by multiplying the industry wage rate by the total burden hours for an estimated costs to respondents of $3570 annually.

13. Estimates of Other Total Annual Cost Burden to Respondents/Recordkeepers or Capital Costs

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

14. Annualized Cost to the Federal Government

The total cost to Federal government is $2,220 (rounded to the nearest dollar). This is calculated by multiplying the total FDA reviewer hours (37) by an average hourly wage of $60 per hour. The table that follows contains a breakdown of costs by each type of voucher.

Guidance for Industry on Tropical Disease Priority Review Vouchers	Total Annual Industry Submissions	FDA Hours to Review Each Submission	Total Hours	Total Cost
Priority Review Voucher Request	1	16	16	$ 960
Notifications of Intent to Use a Voucher	2	8	16	$ 960
Letters Indicating the Transfer of a Voucher Letter	1	2	2	$ 120
Acknowledging the Receipt of a Transferred Voucher	1	2	2	$ 120
Attestation of eligibility	1	1	1	$ 60
Total				$2220

15. Explanation for Program Changes or Adjustments

Based on our evaluation of the information collection since the last OMB review and approval, the burden estimate decreased by 46 hours based on receipt of fewer vouchers request and other information collection activities.

16. Plans for Tabulation and Publication and Project Time Schedule

No plans for tabulation or publication are associated with the information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of the OMB expiration date is appropriate. Consistent with established practice, FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page which will include a link to OMB's website that will identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.