



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0418]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tropical Disease Priority Review Vouchers

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 0910-0822. 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.

Tropical Disease Priority Review Vouchers

This information collection supports implementation of statutory requirements as discussed in Agency guidance. Section 524 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360n) is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world and makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease products. Section 524 of the FD&C Act serves to stimulate new drug development for drugs to 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. As defined in section 524(a)(4) of the FD&C Act, a sponsor of a “tropical disease product application” 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) (42 U.S.C. 262).

Accordingly, we developed the procedural guidance document entitled, “Tropical Disease Priority Review Vouchers” (October 2016), (available 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 priority review voucher based on eligibility criteria set forth in the statute, how to use priority review vouchers, and how priority review vouchers may be transferred to other sponsors. The guidance also communicates that section 524 of the FD&C Act requires attestation by the sponsor of eligibility for a priority review voucher upon submission of the marketing application.

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

In the *Federal Register* of May 1, 2025 (90 FR 18680) we published a 60-day notice soliciting comment on the proposed collection of information. Comments received supported that the collection of information provided utility to FDA and encouraged its continued use. The

comments also suggested FDA consider a broader scope of information collection and greater use of technological submission mechanisms. We appreciate all comments and are committed to making enhancements to our collection systems as our limited resources allow. At the same time, the comments suggested no adjustment in FDA’s estimate of burden for the information collection.

We estimate the burden of the information collection as follows:

Table 1--Estimated Annual Reporting Burden¹

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.

Based on our evaluation of the information collection since the last OMB review and approval, the burden estimate decreased based on receipt of fewer vouchers and other information collection activities. Our estimated burden for the information collection reflects an overall decrease of 46 hours and a decrease of 8 responses.

Dated: July 23, 2025.

Grace R. Graham

Deputy Commissioner for Policy, Legislation, and International Affairs.