4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. FDA-2008-D-0530

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: Fax written comments 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 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. All comments should be identified with the OMB control number 0910-0822. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, 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

OMB Control Number 0910-0822--Revision

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. By enacting section 524 of the FD&C Act, Congress intended to stimulate new drug development for drugs to treat certain tropical diseases for which there are no or few available treatments 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 human drug application for a qualified tropical disease may be eligible for a voucher that can be used to obtain a priority review for any 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 (the PHS Act).

Accordingly, we have developed the guidance document entitled, "Guidance for Industry (GFI): Tropical Disease Priority Review Vouchers." The guidance explains how FDA will implement the provisions of section 524 of the FD&C Act, how sponsors may use priority review vouchers, and how priority review vouchers may be transferred to other sponsors. The guidance also explains eligibility criteria for tropical disease drug product applications submitted under section 505(b)(1) of the FD&C Act and section 351 of the PHS Act, and provides instructions to sponsors on how they may:

- request a priority review voucher; and

- notify FDA of their intent to use a priority review voucher, including the date on which the sponsor intends to submit the application.

The guidance also explains that transfer of a priority review voucher from one sponsor to another is permitted and that each transfer should be documented with a letter of transfer. Finally, the guidance will be revised to include new information collection established by section 611 of the FDA Reauthorization Act of 2017 (FDARA). As amended, section 524 of the FD&C Act requires the sponsor of a tropical disease product application to include an attestation regarding its eligibility for a priority review voucher. The guidance is available at https://www.fda.gov/downloads/Drugs/Guidances/UCM080599.pdf.

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 November 7, 2018 (83 FR 55720), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

Table 1--Estimated Annual Reporting Burden[1]

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Priority Review Voucher Request	5	1	5	8	40
Notifications of Intent to Use a Voucher	5	1	5	8	40
Letters Indicating the Transfer of a Voucher Letter	2	1	2	8	16
Acknowledging the Receipt of a Transferred Voucher	2	1	2	8	16
Attestation of Eligibility	5	1	5	2	10
Total					122

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

We have increased our burden estimate since last approval to account for attestations added by FDARA; however, all other information collection elements remain unchanged.

Dated: April 10, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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