proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–1045 Medicare Uniform Institutional Provider Bill and Supporting Regulations in 42 CFR 424.5

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Uniform Institutional Provider Bill and Supporting Regulations in 42 CFR 424.5; *Use:* Section 42 CFR 424.5(a)(5) requires providers of services to submit a claim for payment prior to any Medicare reimbursement. Charges billed are coded by revenue codes. The bill specifies diagnoses according to the International Classification of Diseases, Tenth Edition (ICD–10) code. Inpatient procedures are identified by ICD–10 codes, and outpatient procedures are described using the CMS Common Procedure Coding System (HCPCS). These are standard systems of identification for all major health insurance claims payers. Submission of information on the UB–04 CMS–1450 permits Medicare Part A MACs to receive consistent data for proper payment. Medicare receives over 99.97 percent of the claims submitted by institutional providers electronically. CMS only accepts electronic claims in the Accredited Standards Committee (ASC) Health Insurance Portability and Accountability Act (HIPAA) 837 format for institutional providers unless the provider meets CMS requirements to submit paper claims. With the uniform bill, we have been able to achieve a more uniform and a more automated bill processing system for Medicare institutional and providers. The UB–04 CMS–1450 is managed by the National Uniform Billing Committee (NUBC), sponsored by the American Hospital Association. Most payers are represented on this body, and the UB–04 is widely used in the industry. Medicare Part A MACs use the information on the UB–04 CMS–1450 to determine whether to make Medicare payment for the services provided, the payment amount, and whether or not to apply deductibles to the claim. The same method is also used by other payers. CMS is also a secondary user of data. CMS uses the information to develop a database, which is used to update, and revise established payment schedules and other payment rates for covered services. CMS also uses the information to conduct studies and reports. *Form Number:* CMS–1045 (OMB control number: 0938–0997); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 53,111; *Total Annual Responses:* 204,138,881; *Total Annual Hours:* 1,797,958. (For policy questions regarding this collection contact Mohammad B Ullah at 410–786–4143.)

Dated: April 10, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–07491 Filed 4–15–19; 8:45 am]

BILLING CODE 4120–01–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 May 16, 2019.

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	Number of respondents	Number 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.

[FR Doc. 2019–07464 Filed 4–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0597]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 May 16, 2019.

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 0910–0733. 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.

Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring—21 CFR Parts 312 and 812

OMB Control Number 0910–0733—Extension

This information collection supports reporting and recordkeeping found in Agency guidance. Under parts 312 and 812 (21 CFR parts 312 and 812), sponsors are required to provide appropriate oversight of their clinical investigations to ensure adequate protection of the rights, welfare, and safety of human subjects and to ensure the quality and integrity of the resulting data submitted to FDA. As part of this oversight, sponsors of clinical investigations are required to monitor the conduct and progress of their clinical investigations. The regulations do not specify how sponsors are to