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

conduct monitoring of clinical investigations and are, therefore, compatible with a range of approaches to monitoring.

Accordingly, we developed the guidance document entitled ''Guidance for Industry—Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring'' (available at: *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm269919.pdf*). The guidance is intended to assist sponsors of clinical investigations in developing strategies for risk-based monitoring and plans for clinical investigations of human drug and biological products, medical devices, and combinations thereof. The guidance describes strategies for monitoring activities performed by sponsors or by contract research organizations (CROs) that focus on the conduct, oversight, and reporting of findings of an investigation by clinical investigators. The guidance also recommends strategies that reflect a risk-based approach to monitoring that focuses on critical study parameters and relies on a combination of monitoring activities to oversee a study effectively. Finally, the guidance specifically encourages greater reliance on centralized monitoring methods where appropriate.

Information collections for reports and records associated with clinical investigations under parts 312 and 812 are currently approved under OMB control numbers 0910–0014 and 0910–0078, respectively. These reporting and recordkeeping provisions cover general elements. The guidance discusses other elements sponsors and investigators should consider and include in developing a monitoring plan. As explained in the guidance, documentation of monitoring should include sufficient detail to allow verification that the monitoring plan was followed. The plan should provide adequate information to those involved with monitoring to effectively carry out their duties. All sponsor and CRO personnel who may be involved with monitoring (including those who review appropriate action, determine appropriate action, or both) regarding potential issues identified through monitoring should review the monitoring plan.

In the **Federal Register** of November 30, 2018 (83 FR 61646), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however, it was not responsive to any of the four information collection topics solicited in the notice.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Activity | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Documentation included in comprehensive monitoring plan | 88 | 1.5 | 132 | 4 | 528 |

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

Based on a review of the information collection, we have made no adjustments to our burden estimate. We estimate 88 sponsors will develop 132 comprehensive monitoring plans in accordance with the guidance. We believe the associated burden for each plan is approximately 4 hours and includes the time necessary to develop, and amend as appropriate, the monitoring plan.

Dated: April 10, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–07523 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–2018–N–4839]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Registering With the Center for Veterinary Medicine's Electronic Submission System

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Center for Veterinary Medicine (CVM) Guidance for Industry (GFI) #108 entitled ''Registering with CVM's Electronic Submission System.''

**DATES:** Submit either electronic or written comments on the collection of information by June 17, 2019.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 17, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 17, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you