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

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–4839 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Registering with the Center for Veterinary Medicine's Electronic Submission System.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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. ''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 (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Registering With the Center for Veterinary Medicine's Electronic Submission System—21 CFR 11.2

OMB Control Number 0910–0454—Extension

FDA's Electronic Records; Electronic Signatures regulation (21 CFR part 11) requires that we identify in the Electronic Submission Docket (Docket No. FDA–1992–S–0039) the types of documents or parts of documents acceptable for official electronic submission. FDA's CVM has placed notifications in that docket identifying documents acceptable for electronic submission to the Center, as required by 21 CFR 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of FDA's Electronic Records; Electronic Signatures regulation.

The FDA Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of premarket and postmarket regulatory information for review. The FDA ESG is the central transmission point for sending information electronically to FDA. Within that context, the FDA ESG is a conduit along which submissions travel to reach the proper FDA Center or Office. CVM's Electronic Submission System (ESS) is a Center-wide solution for accepting electronic regulatory submissions. The CVM ESS is used to accept electronic submissions for animal and veterinary products.

Our guidance entitled ''Guidance for Industry (GFI) #108: Registering with the Center for Veterinary Medicine's Electronic Submission System'' outlines general standards to be used for the submission of any electronic information to CVM using the FDA ESG, including how to register with the CVM ESS using Form FDA 3538, Electronic Submission System Participant Management Form.

The reporting associated with new animal drug applications and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(1)). We use the information collected to review the data, labeling and manufacturing controls and procedures to evaluate the safety and effectiveness of the proposed new animal drug. The reporting associated with new animal drug applications is approved under OMB control number 0910–0032. Respondents use GFI #108

and Form FDA 3538 to facilitate the electronic submission of such information. We use the information collected with Form FDA 3538 to register respondents to use the CVM ESS.

Description of Respondents: The respondents are sponsors of new animal drug applications.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
11.2	Form FDA 3538	179	1.3	233	.08 (5 minutes)	19

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

We base our estimates on our experience with the submission of electronic information using the CVM ESS and the number of electronic registration or change requests received between January 1, 2018, and November 30, 2018. Our estimated burden for the information collection reflects an overall increase of 16 hours and a corresponding increase of 195 responses. We attribute this adjustment to the reauthorizations of both the Animal Drug User Fee Act and the Animal Generic Drug User Fee Act, which require sponsors to submit information electronically to the CVM's Office of New Animal Drug Evaluation. Because of this requirement, sponsors are now registering to use the CVM ESS in greater numbers than in previous years.

Dated: April 10, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–07468 Filed 4–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–N–0742; FDA–2018–N–1967; FDA–2018–N–2970; FDA–2017–N–1779; FDA–2008–N–0500; FDA–2012–N–0129; FDA–2009–D–0268; FDA–2014–D–0609; and FDA–2011–N–0776]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	0910–0045	12/31/2021
Biosimilar User Fee Program	0910–0718	12/31/2021
Surveys and Interviews with Investigational New Drug Sponsors to Assess Current Communication Practices with FDA Review Staff Under the Sixth Authorization of the Prescription Drug User Fee Act	0910–0863	12/31/2021
Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion	0910–0864	12/31/2021
Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products	0910–0572	1/31/2022
General Licensing Provisions; Section 351(k) Biosimilar Applications	0910–0719	1/31/2022
Labeling of Certain Beers Subject to the Labeling Jurisdiction of the FDA	0910–0728	1/31/2022
Implementation of the Drug Supply Chain Security Act—Identification of Suspect Product and Notification	0910–0806	1/31/2022
Reclassification Petitions for Medical Devices	0910–0138	2/28/2022

Dated: April 10, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–07467 Filed 4–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,