when determining priorities for updating guidance documents and will revise these as resources permit.

Consistent with the Good Guidance Practices regulation at 21 CFR 10.115(f)(4), CDRH would appreciate suggestions that CDRH revise or withdraw an already existing guidance document. We request that the suggestion clearly explain why the guidance document should be revised or withdrawn and, if applicable, how it should be revised. While we are requesting feedback on the list of previously issued final guidances located in the annual agenda website, feedback on any guidance is appreciated and will be considered.

In FY 2019, CDRH received comments regarding guidances issued in 2009, 1999, and 1989, and has withdrawn three guidance documents in response to comments received and because these guidance documents were determined to no longer represent the Agency's current thinking. The revision of several guidance documents is also being considered as resources permit.

III. Website Location of Guidance Lists

This notice announces the website location of the document that provides the A and B lists of guidance documents, which CDRH is intending to publish during FY 2020. To access these two lists, visit FDA's website at *https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidance-development.* We note that the topics on this and past guidance priority lists may be removed or modified based on current priorities, as well as comments received regarding these lists. Furthermore, FDA and CDRH priorities are subject to change at any time (*e.g.,* newly identified safety issues). The Agency is not required to publish every guidance on either list if the resources needed would be to the detriment of meeting quantitative review timelines and statutory obligations. In addition, the Agency is not precluded from issuing guidance documents that are not on either list.

Dated: October 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22370 Filed 10–11–19; 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; Submission for Office of Management and Budget Review; 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 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 November 14, 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 0910–0454. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

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 Center for Veterinary Medicine (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. The 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 for Industry (GFI) #108 entitled ''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.'' Registering with the CVM ESS allows respondents to send electronic regulatory submissions to the Office of New Animal Drug Evaluation, the Office of Surveillance and Compliance's Division of Animal Feeds and Division of Surveillance, and the Office of Minor Use and Minor Species Animal Drug Development.

Respondents use GFI #108 and Form FDA 3538 to facilitate the electronic submission of regulatory information. We use the information collected with Form FDA 3538 to register respondents to use the CVM ESS.

Description of Respondents: The respondents are submitters of regulatory information to CVM.

In the **Federal Register** of April 16, 2019 (84 FR 15621), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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	193	1.3	251	0.08 (5 minutes)	20

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

In the 60-day notice published April 16, 2019, we based our estimate of 179 respondents per year 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. We are now adjusting our estimate to 193 respondents per year to better reflect the data for the time period January 1 to December 31, 2018. Using these new figures, our estimated burden for the information collection reflects an overall increase from the previous OMB approval of 17 hours and a corresponding increase of 213 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: October 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22371 Filed 10–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0086]

Agency Information Collection Activities; Proposed Collection; Comment Request; Potential Tobacco Product Violations Reporting Form

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 Potential Tobacco Product Violations Reporting Form.

DATES: Submit either electronic or written comments on the collection of information by December 16, 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 December 16, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 16, 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–2014–N–0086 for ''Potential Tobacco Product Violations Reporting Form.'' 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