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 We request that the suggestion clearly explain why the guidance document should be revised or withdrawn and, if applicable, how it should be revised.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 also 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In FY 2019, CDRH received comments regarding guidances issued in 2009, 1999, and 1989, and has withdrawn three guidance documents in response to comments received and because these guidance documents were determined to no longer represent the Agency’s current thinking.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/cdhr-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
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 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 “CONFIDENTIAL INFORMATION.” 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

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

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.