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

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: 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: 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.

Potential Tobacco Product Violations Reporting Form

OMB Control Number 0910–0716—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended section 201 *et seq.* of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321 *et seq.*) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. FDA is requesting an extension of OMB approval for the collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act.

FDA created a Tobacco Call Center (with a toll-free number: 1–877–CTP–1373). Callers can report potential violations of the Tobacco Control Act, and FDA may conduct followup investigations based on information received. When callers report a violation, the caller will be asked to provide as much certain information as they can recall, including: The date the potential violation occurred; product type (*e.g.,* cigarette, smokeless, roll-your-own, cigar, e-cigarette, hookah, pipe tobacco); tobacco brand; potential violation type; type of potentially violative promotional materials; who potentially violated; and the name, address, phone number, and email address of the potential violator. The caller will also be asked to list the potential violator's website (if available), describe the potential violation, and provide any additional files or information pertinent to the potential violation.

FDA currently provides a form that may be used to solicit this information from the caller (Form FDA 3779, Potential Tobacco Product Violations Report), and seeks renewal of Form FDA 3779. This form is posted on FDA's website. The public and interested stakeholders are also able to report information regarding possible violations of the Tobacco Control Act through the following methods: Calling the Tobacco Call Center using the Center for Tobacco Products (CTP) toll-free number; using a fillable Form FDA 3779 found on FDA's website; downloading a PDF version of the form to send via email or mail to FDA; requesting a copy of Form FDA 3779 by contacting CTP and sending by mail to FDA; and sending a letter to FDA's CTP.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity and FDA Form 3779	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting violations of the FD&C Act, as amended by the Tobacco Control Act via telephone, internet form, mail, smartphone application, or email.	750	2	1,500	0.25 (15 minutes).	375

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

FDA estimates that submitting the information (by telephone, internet form, paper form by mail, or email) will take 0.25 hour (*i.e.,* 15 minutes) per response. This estimate is based on the type and rate of reporting that has been submitted through the Potential Tobacco Violation Reporting Form in the past.

FDA estimates the number of annual respondents to this collection of information will be 750, who will each submit 2 reports by telephone, internet form, paper form, or email. Each report is expected to take 0.25 hour to complete and submit; therefore, total burden hours for this collection of information is estimated to be 375 hours (1,500 responses × 0.25 hour per response).

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: October 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22335 Filed 10–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Ending the HIV Epidemic (EHE) Triannual Module, OMB No. 0906–xxxx—New.

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than December 16, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Ending the HIV Epidemic (EHE) Triannual Module, OMB No. 0906–xxxx—New.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low income people with HIV. Nearly two-thirds of clients (patients) live at or below 100 percent of the Federal poverty level and approximately three-quarters of RWHAP clients are racial/ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of safety net providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people with diagnosed HIV in the United States.

Ending the HIV Epidemic: A Plan for America

In February 2019, the Administration announced a new initiative, *Ending the HIV Epidemic: A Plan for America* (EHE). Authorized by section 311(c) and title XXVI of the Public Health Service Act, this ten-year initiative beginning in FY 2020 seeks to achieve the important goal of reducing new HIV infections in the United States to less than 3,000 per year by 2030. EHE will focus on 48 counties, Washington, DC, San Juan, Puerto Rico, and seven states that have a substantial rural HIV burden. By focusing on these jurisdictions in the first phase of the EHE, HHS plans to reduce new HIV infections by 75% within five years. Across the United States, the EHE will promote and implement four Pillars to substantially reduce HIV transmissions—diagnose, treat, prevent, and respond. EHE is a collaborative effort among key HHS agencies, primarily HRSA, the Centers for Disease Control and Prevention, the National Institutes of Health, the Indian Health Service, and the Substance Abuse and Mental Health Services Administration. RWHAP will focus on implementing activities in the *Pillar Two: Treat* and supporting *Pillar Four: Respond* for this important initiative.

HRSA identified proposed data collection needs to support HRSA's efforts towards ending the HIV Epidemic. In order to reach this goal, HRSA needs to have the ability to monitor initiative activities including funding allocations, expenditures, service utilization, and clients served; and assess progress toward meeting national goals for ending the HIV epidemic. HRSA proposes that recipients and service providers (subrecipients) who receive EHE initiative funding report on the reach of EHE initiative activities in a new EHE Triannual Module.

Need and Proposed Use of the Information: HRSA proposes that service providers who receive EHE Initiative funding report aggregate information on the number of clients receiving specific services and the number of clients who were prescribed antiretroviral medications in the previous four months (beginning in March 2020). This information would complement the annual information collected through the Ryan White Services Report (RSR) and other reporting mechanisms. Service providers will report three times per year on clients who received at least one service during the previous four month period.

This module will provide HRSA with frequent and timely data on EHE Initiative progress by providing information on the number of clients who are reached through the EHE Initiative during each four month reporting period. In addition, HRSA can calculate the number of clients who did not receive services in the previous year by subtracting the number of clients who received services in the previous year and the number of new clients from the total number of clients. This will provide valuable information on the scope of outreach to new clients and clients who have had a lapse in service which could be an indication of re-engagement in care. These calculations will be similar to calculations using the new RSR variables. This module will support project officer monitoring and HRSA's understanding of service provision.

Likely Respondents: RWHAP Part A and Part B Recipients and Subrecipients funded by the EHE Initiative.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.