

proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*ACF Certifying Officer.*

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**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Assets for Independence Program Performance Progress Report.  
*OMB No.:* New.

*Description:* The Assets for Independence (AFI) Act (Title IV of the Community Opportunities, Accountability, and Training and Educational Services Act of 1998, Pub. L. 105-285, [42 U.S.C. 604 note]) requires that organizations operating AFI projects submit annual progress reports.

This request is to create an AFI program specific Performance Progress Report (PPR) to replace the semiannual standard form performance progress report (SF-PPR) and the annual data

report. The AFI PPR will collect data on project activities and attributes similar to the reports that it is replacing. The Office of Community Services (OCS) in the Administration for Children and Families (ACF) will use the data collected in the AFI PPR to prepare the annual AFI Report to Congress, to evaluate and monitor the performance of the AFI program overall and of individual projects, and to inform and support technical assistance efforts. The AFI PPR would fulfill AFI Act reporting requirements and program purposes.

The AFI PPR will be submitted quarterly: three times per year using an abbreviated short form and one time using a long form. Both draft data collection instruments are available for review online at <http://idaresources.acf.hhs.gov/AFIPPR>.

Respondents: Assets for Independence (AFI) program grantees.

Annual Burden Estimates:

Form name	Number of responses	Number of responses per respondent	Average burden hours per response	Total burden hours
AFI PPR Short Form .....	300	3	0.5	450
AFI PPR Long Form .....	300	1	3.8	1,140
Estimated Annual Burden Hours .....				1,590

**Additional Information**

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

**OMB Comment**

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0519]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How To Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, 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 (the 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 extending Office

of Management and Budget (OMB) approval on the existing reporting requirements relating to how one may submit information electronically to the Center for Veterinary Medicine (CVM) using the FDA Electronic Submissions Gateway (ESG).

**DATES:** Submit either electronic or written comments on the collection of information by June 7, 2016.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2013-N-0519 for “Guidance for Industry on How To Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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 How To Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway—21 CFR 11.2 OMB Control Number 0910-0454—Extension**

We accept certain types of submissions electronically with no requirement for a paper copy. These types of documents are listed in public docket 97S-0251 as required by 21 CFR 11.2. Our ability to receive and process information submitted electronically is limited by our current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. Our guidance entitled “Guidance for Industry #108: How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway” outlines general standards to be used for the submission of any electronic information to CVM using the FDA ESG. The likely respondents are sponsors for new animal drug applications.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

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 .....	3538	29	1.3	38	.08 (5 minutes) .....	3.0

<sup>1</sup> 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 to us using the FDA ESG and the number of electronic registration or change requests received between January 1, 2014, and December 31, 2014.

Dated: April 1, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than May 9, 2016.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer

Data to Verify 340B Drug Pricing Program Ceiling Price Calculations.

#### OMB No. 0915-0327—Revision

**Abstract:** Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992, enacted as Section 340B of the Public Health Service Act (PHS Act; “Limitation on Prices of Drugs Purchased by Covered Entities”), provides that the Secretary of Health and Human Services will enter into a Pharmaceutical Pricing Agreement (PPA) with each manufacturer of covered outpatient drugs in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price decreased by a rebate percentage. Under this PPA, a manufacturer agrees not to charge a price for covered outpatient drugs that exceeds an amount determined under a statutory formula (ceiling price). A manufacturer subject to a PPA must offer all covered outpatient drugs at no more than the ceiling price to a covered entity listed in the 340B Program database if such drug is made available to any other purchaser at any price. The manufacturer shall rely on the information in the 340B database to determine if the covered entity is participating in the 340B Program or for any notifications of changes to eligibility that may occur within a quarter. By signing the PPA, the manufacturer agrees to comply with all applicable statutory and regulatory requirements. In response to comments submitted during the first public review of this ICR, the language has been revised in this notice and in the draft instruments in order to align with the applicable statutory language regarding the obligation to sign the PPA, the circumstances under which participating manufacturers must offer covered outpatient drugs to covered entities, and the description of the ceiling price data required to be provided.

The purpose of this revision is to include an addendum to the PPA to incorporate the administrative requirement for manufacturer integrity provisions directly addressed in the Affordable Care Act.

**Need and Proposed Use of the Information:** HRSA is proposing revisions to the current PPA to include an addendum in response to manufacturer integrity provisions implemented in the Affordable Care

Act. Section 7102(b) of the Affordable Care Act amends section 340B(a)(1) of the Public Health Service Act (PHSA) to add two new requirements for inclusion in the PPA with manufacturers of covered outpatient drugs:

I. “Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug . . .” and

II. “. . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.”

These requirements shall be included in the PPA addendum to be signed by manufacturers participating in the 340B Program to ensure that the provisions of the 340B statute requiring inclusion in the PPA are satisfied. The execution of the addendum by manufacturers will fulfill the administrative requirement of the statute that these provisions be included in the PPA. The burden imposed on manufacturers by the proposed requirement of the PPA is minimal because the addendum does not impose requirements beyond review and a signature by the manufacturer.

**Likely Respondents:** Drug Manufacturers.

**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 Information Collection Request are summarized in the table below.

**Total Estimated Annualized Burden Hours:**