(OFA) achieve its goals to foster economically secure households and communities for the well-being and long-term success of children and families. The purpose of the PAIVED study is to better understand the prevalence of intimate partner violence (IPV) experienced by the population of fathers served by Responsible Fatherhood (RF) programs, and the services that federally-funded RF programs are providing to address and contribute to the prevention of IPV among its participants. The proposed data collection will include whether IPV content is included in RF programs, the types of activities they are using to address IPV, and related successes and challenges. Other collected data will include barriers to addressing IPV in RF programs, the relevance of addressing IPV with fathers, fathers' reactions to this programming, and what types of partnerships RF programs have with other agencies to address IPV. This information will be collected through interviews conducted over the phone and in-person with RF grantee program staff and community partners. This information will be critical to inform future efforts to address and contribute to the prevention of IPV through RF programming.

Respondents: Responsible Fatherhood grantee program staff (*e.g.,* program directors and facilitators) and community partners.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
RF grantee/community partner screening and participant recruitment	37	1	1	37
RF grantee program staff semi-structured interview	23	1	1.5	35
Community partner semi-structured interview	10	1	1.5	15

Estimated Total Annual Burden Hours: 87.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the 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.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–02476 Filed 2–7–18; 8:45 am]

BILLING CODE 4184–73–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB NO.: 0970–0460]

Proposed Information Collection Activity; Comment Request; Healthy Marriage and Responsible Fatherhood Performance Measures and Additional Data Collection (Part of the Fatherhood and Marriage Local Evaluation and Cross-Site (FaMLE Cross-Site) Project)—Extension

Description

Background

For decades various organizations and agencies have been developing and operating programs to strengthen families through healthy marriage and relationship education and responsible fatherhood programming. The Administration for Children and Families (ACF), Office of Family Assistance (OFA), has had administrative responsibility for federal funding of such programs since 2006 through the Healthy Marriage (HM) and Responsible Fatherhood (RF) Grant Programs. The authorizing legislation for the programs may be found in Section 403(a)(2) of the Social Security Act [1].

Extension of Current Approval

The Offices of Family Assistance (OFA) and Planning, Research and Evaluation (OPRE) in the Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) are proposing to extend performance measure and other data collection activities, in service to the HM and RF programs. This data collection is part of the Fatherhood and Marriage Local Evaluation and Cross-site (FaMLE Cross-site) project, whose purpose is to support high quality data collection, strengthen local evaluations, and conduct cross-site analysis for the Responsible Fatherhood and Healthy Marriage grantees. ACF is requesting comment on the following data collection, which has been ongoing under OMB #0970–0460 since 2016. There are no changes proposed to the information collection, we are only requesting an extension to continue data collection with the current grantees through 2020.

Performance measures. ACF is proposing to extend collection of a set of performance measures that are collected by all grantees. These measures collect standardized information in the following areas:

- Applicant characteristics;
- Program operations (including program characteristics and service delivery); and
- Participant outcomes:
  - Entrance survey, with four versions: (1) Healthy Marriage Program Pre-Program Survey for Adult-Focused Programs; (2) Healthy Marriage Program Pre-Program Survey for Youth-Focused Programs; (3) Responsible Fatherhood

Program Pre-Program Survey for Community-Based-Fathers; and (4) Responsible Fatherhood Program Pre-Program Survey for Incarcerated Fathers.

○ Exit survey, with four versions: (1) Healthy Marriage Program Post-Program Survey for Adult-Focused Programs; (2) Healthy Marriage Program Post-Program Survey for Youth-Focused Programs; (3) Responsible Fatherhood Program Post-Program Survey for Community-Based-Fathers; and (4) Responsible Fatherhood Program Post-Program Survey for Incarcerated Fathers.

These measures were developed per extensive review of the research literature and grantees' past measures.

Grantees are required to submit data on these standardized measures on a regular basis (*e.g.,* quarterly). In addition to the performance measures mention above, ACF proposes to extend collection for these data submissions:

- Semi-annual Performance Progress Report (PPR), with two versions: (1) Performance Progress Report for Healthy Marriage Programs, and (2) Performance Progress Report for Responsible Fatherhood Programs; and
- Quarterly Performance Report (QPR), with two versions: (1) Quarterly Performance Progress Report for Healthy Marriage Programs, and (2) Quarterly Performance Progress Report for Responsible Fatherhood Programs.

A management information system has been implemented which improves efficiency and the quality of data, and makes reporting easier.

Additional data collection. We also seek to extend the approval to collect information from a sub-set of grantees on how they designed and implemented their programs (information on outcomes associated with programs will also be assessed), per the following protocols:

- Staff interview protocol on program design (will be collected from about half of all grantees);
- Staff interview protocols on program implementation (will be collected from about 10 grantees); and
- Program participant focus group protocol (will be conducted with about 10 grantees).

Respondents: Responsible Fatherhood and Healthy Marriage Program grantees (*e.g.,* grantee staff) and program applicants and participants—participants are called ''clients.''

ANNUAL BURDEN ESTIMATES

Instrument	Respondent	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Data Collection by Grantees (DCS, or Data Collected by Sites)						
Instrument DCS–1: Applicant characteristics.	Program applicants	265,838	87,504	1	0.25	21,876
	Program staff	360	360	243	0.10	8,750
Instrument DCS–2: Grantee program operations.	Program staff	120	120	1	0.75	90
Instrument DCS–3: Service receipt in MIS.	Program staff	1,540	1,540	156	0.50	39,916
Instrument DCS–4: Entrance and Exit Surveys.	Program clients (Entrance Survey; 4 versions).	239,493	79,831	1	0.42	33,529
	Program clients (Exit Survey; 4 versions).	132,087	44,029	1	0.42	18,492
	Program staff (Entrance and Exit surveys on paper).	60	20	1,285	0.30	7,712
Instrument DCS–5: Semi-annual report.	Program staff (2 versions)	120	120	2	3	720
Instrument DCS–6: Quarterly performance report.	Program staff (2 versions)	120	120	2	1	240
Data Collection by the Contractor (DCI, or Data collected by the Contractor Itself)						
Instrument DCI–1: Topic guide on program design.	Program staff	60	20	1	1	20
Instrument DCI–2: Topic guide on program implementation.	Program staff	300	100	1	1	100
Instrument DCI–3: Focus group protocol.	Program clients	801	267	1	1.50	401

Estimated Total Annual Burden Hours: 131,846.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the 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.

Reference

[1] *http://www.ssa.gov/OP_Home/ssact/title04/0403.htm.*

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2018–02494 Filed 2–7–18; 8:45 am]

BILLING CODE 4184–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–E–1664]

Determination of Regulatory Review Period for Purposes of Patent Extension; JUBLIA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for JUBLIA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 9, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 7, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 April 9, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 9, 2018. 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–2015–E–1664 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; JUBLIA.'' 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.