ANNUAL BURDEN ESTIMATES—Continued

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| Home Visitor Interview | 270 | 1 | .25 | 68 |
| Primary Caregiver/Home Visitor Child Rating | 450 | 3.2 | .333 | 480 |
| Family Service Tracking | 450 | 166 | .125 | 9,360 |
| Child Direct Assessment | 774 | 1 | 1 | 774 |
| Parent-Child Interaction | 774 | 1 | .25 | 194 |
| Estimated Total Annual Burden Hours | | | | 12,460 |

**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:* OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection.

*E-mail address: OPREinfocollection@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, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: July 1, 2011.

**Steven M. Hanmer,**

*Reports Clearance Officer.*

[FR Doc. 2011–16976 Filed 7–7–11; 8:45 am]

**BILLING CODE 4184–03–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Submission for OMB Review; Comment Request

*Title:* Evaluation of Adolescent Pregnancy Prevention Approaches—First Follow-up Data Collection.

*OMB No.:* ICRAS: 0970–0360.

*Description:* The Office of Adolescent Health (OAH), Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS), is overseeing and coordinating adolescent pregnancy prevention evaluation efforts as part of the Teen Pregnancy Prevention Initiative. OAH is working collaboratively with the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Centers for Disease Control and Prevention (CDC), and the Administration for Children and Families (ACF) on adolescent pregnancy prevention evaluation activities.

The Evaluation of Adolescent Pregnancy Prevention Approaches (PPA) is one of these efforts. PPA is a random assignment evaluation which will expand available evidence on effective ways to reduce teen pregnancy. The evaluation will document and test a range of pregnancy prevention approaches in up to eight program sites. The findings from the evaluation will be of interest to the general public, to policy-makers, and to organizations interested in teen pregnancy prevention.

This request for comment follows on a 60-Day **Federal Register** Public Comment Request Notice, published on Monday, July 12, 2010, pp. 39695–39696, with the document identifier of OS–0990–New.

This proposed information collection activity focuses on collecting follow-up data from a self-administered questionnaire which will be analyzed to determine program effects. Through a survey instrument, respondents will be asked to answer questions about demographics and risk and protective factors related to teen pregnancy.

Respondents: The data will be collected through private, self-administered questionnaires completed by study participants, i.e. adolescents assigned to a select school or community teen pregnancy prevention program or to a control group. Surveys will be distributed and collected by trained professional staff.

ANNUAL BURDEN ESTIMATES

| Instrument | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Total annual burden hours |
|---|---|---|---|---|
| Chicago Public Schools/Health Teacher | 430 | 1 | .5 | 215 |
| Oklahoma Institute of Child Advocacy/Power Through Choices | 306 | 1 | .6 | 184 |
| Estimated Total Annual Burden Hours | | | | 399 |

**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:* OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *OPREinfocollection@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, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: July 1, 2011.

**Steven Hanmer,**

*OPRE Reports Clearance Officer.*

[FR Doc. 2011–16974 Filed 7–7–11; 8:45 am]

**BILLING CODE 4150–30–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0237]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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 August 8, 2011.

**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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0646. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@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.

### Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs—(OMB Control Number 0910–0646)—Extension

In the **Federal Register** of July 28, 2009 (74 FR 37163), FDA published a final rule that required the holder of a new drug application (NDA) to notify the Agency if an authorized generic drug is marketed by clearly including this information in annual reports in an easily accessible place and by sending a copy of the relevant portion of the annual reports to a central contact point. We took this action as part of our implementation of the Food and Drug Administration Amendments Act, which requires that FDA publish a list of all authorized generic drugs included in an annual report after January 1, 1999, and that the Agency update the list quarterly. We initially published this list on June 27, 2008, on the Internet and notified relevant Federal Agencies that the list was published, and we will continue to update it.

During the past several years, FDA has been reviewing annual reports it has received under § 314.81(b)(2) (21 CFR 314.81(b)(2)) to discern whether an authorized generic drug is being marketed by the NDA holder. Based on information learned from this review and based on the number of annual reports the Agency currently receives under § 314.81(b)(2), we estimate that we will receive approximately 400 annual reports containing the information required under § 314.81(b)(2)(ii)(*b*), for authorized generic drugs that were marketed during the time period covered by an annual report submitted after January 1, 1999. Based on the number of sponsors that currently submit annual reports, we estimate that approximately 60 sponsors will submit these 400 annual reports with authorized generics. As indicated in table 1 of this document, we are estimating that the same number of annual reports will be submitted each year from the same number of sponsors containing the information required under § 314.81(b)(2)(ii)(*b*), and that the same number of copies of that portion of each annual report containing the authorized generic drug information will be submitted from the same number of sponsors. Concerning the hours per response, based on our estimate of 40 hours to prepare each annual report currently submitted under § 314.81(b)(2), we estimate that sponsors will need approximately 1 hour to prepare the information required under § 314.81(b)(2)(ii)(*b*) for each authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999; approximately 15 minutes to prepare the information required under § 314.81(b)(2)(ii)(*b*) for each subsequent annual report; and approximately 3 minutes to submit to FDA a copy of that portion of each annual report containing the authorized generic drug information.

In the **Federal Register** of April 13, 2011 (76 FR 20677), 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 314.81(b)(2)(ii)(*b*) | Number of respondents | Number of reponses per respondent | Total annual responses | Average burden per response (in hours) [2] | Total hours |
|---|---|---|---|---|---|
| Authorized generic drug information on first marketed generics in an annual report | 60 | 6.7 | 400 | 1 | 400 |
| Authorized generic drug information submitted in each subsequent annual report | 60 | 6.7 | 400 | 15/60 | 100 |
| The submission of a copy of that portion of each annual report containing authorized generic drug information | 60 | 6.7 | 400 | 3/60 | 20 |