revision that will assess errors in eligibility determinations that will compare the amount authorized for payment with the actual payment.

Respondents: State grantees, the District of Columbia, and Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Sampling Decisions and Fieldwork Preparation Plan	17	1	106	1802
Record Review Worksheet	17	276	6.33	29,700.36
State Improper Authorizations for Payment Report	17	1	639	10,863
Corrective Action Plan	8	1	156	1248
Estimated Total Annual Burden Hours:				43,613.36

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*.

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: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–17681 Filed 7–19–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: Comment Request

Title: Innovative Strategies for Increasing Self-Sufficiency: Follow-Up Data Collection.

OMB No.: 0970–0397.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as part of the Innovative Strategies for Increasing Self-Sufficiency (ISIS) demonstration and evaluation. The ISIS project will test a range of promising career pathways strategies to promote education, employment, and self-sufficiency. The major goals of the ISIS project include increasing the empirical knowledge about the effectiveness of a variety of programs for low-income individuals and families to achieve educational credentials, attain employment and advance to positions that enable self-sufficiency, as well as producing useful findings for both policymakers and program administrators.

This proposed information collection activity focuses on collecting follow-up data elements approximately one year after program enrollment. (Baseline data elements were previously collected at the time of program enrollment. A baseline information form captured basic identification, demographic, and contact information from program participants; a self-administered questionnaire captured additional information about participants related to the project goals; and baseline implementation data collection interviews collected information from knowledgeable informants about the service context for each evaluation site using a baseline implementation guide. These instruments were previously approved under OMB No. 0970–0397).

The purpose of this information collection effort is to follow up with study participants, document the experiences of program participants, examine differences in service receipt and educational experiences between program and control group members, describe the intervention as it was implemented in each site and assess the extent to which it was implemented as intended, and assess the implications for intervention scalability and sustainability.

Specifically, this data will be collected using the following instruments: (a) A follow-up survey which will be administered to all study participants approximately one year following enrollment in the study; (b) tracking letters which will be sent every four months to all study participants requesting an update of their contact information; (c) a modification to the Baseline Information Form requesting some basic information about all of the study participant's children (if applicable); (d) interview guides for the in-person visits to the intervention sites to structure discussions with program leadership/managers, instructional staff, case managers/advisors, partners and employers; (e) a brief survey for instructional staff; (f) a brief survey for case managers/advisors; and (g) in-depth interviews with a sample of study participants.

Respondents: Individuals enrolled in the ISIS demonstration programs, control group members, ISIS program/partner staff (including program leadership, case managers and instructional staff), and other local informants.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
12 Month Follow-up Survey	3,600	1	0.833	2,999
Tracking Letters	10,800	3	0.083	2,689
Baseline Information Form (Modification)	3,500	1	0.05	175
Program Leadership/Managers Interview Guide	13	1	2	26
Instructional Staff Interview Guide	21	1	2	42
Case Managers/Advisors Interview Guide	16	1	2	32
Partners Interview Guide	16	1	2	32
Employers Interview Guide	19	1	1	19
Instructional Staff Survey	26	1	0.5	13
Case Managers/Advisors Survey	24	1	0.5	12
Study Participant Interview Guide	80	1	1	80

Estimated Total Annual Burden Hours: 6,119.

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, 370 L'Enfant Promenade SW., Washington, DC 20447, 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.

Robert Sargis,

Reports Clearance Officer, Administration for Children and Families.

[FR Doc. 2012–17641 Filed 7–19–12; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0247]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

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 20, 2012.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0429. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@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.

Guidance for Industry on Formal Meetings with Sponsors and Applicants for Prescription Drug User Fee Act (PDUFA) Products—(OMB Control Number 0910–0429)—(Extension)

This information collection approval request is for FDA guidance on the procedures for formal meetings between FDA and sponsors or applicants regarding the development and review of PDUFA products. The guidance describes procedures for requesting, scheduling, conducting, and documenting such formal meetings. The guidance provides information on how the Agency will interpret and apply section 119(a) of the Food and Drug Administration Modernization Act (FDAMA), specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82 (21 CFR 312.47 and 312.82)).

The guidance describes two collections of information: The submission of a meeting request containing certain information and the submission of an information package in advance of the formal meeting. Agency regulations at § 312.47(b)(1)(ii), (b)(1)(iv), and (b)(2) describe information that should be submitted in support of a request for an End-of-Phase 2 meeting and a Pre-NDA meeting. The information collection provisions of § 312.47 have been approved by OMB (OMB control number 0910–0014). However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is submitting additional estimates for OMB approval.