Estimated Total Annual Burden Hours: 3,149,174.

Authority: 42 U.S.C. 9836A.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–17870 Filed 8–19–19; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; American Indian and Alaska Native (AIAN) Facility Survey (New Collection)

AGENCY: The Office of Head Start; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office Head Start (OHS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data on the condition and ownership of American Indian and Alaska Native (AIAN) facilities to meet congressional reporting requirements under the Head Start Act.

DATES: *Comments due within 30 days of publication.* 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.

ADDRESSES: 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*, Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained 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. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Head Start Act at Sec. 650(b) requires the submission of a report to the Committee on Education and Labor of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate concerning the condition, location, and ownership of facilities used by AIAN grantees. This report is required once during every 5-year period. The proposed collection is a brief survey on the condition and ownership of AIAN facilities for the purpose of this report.

Respondents: AIAN Head Start grantees

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
AIAN Facility Survey	155	3.5	.1	54.25

Estimated Total Annual Burden Hours: 54.25.

Authority: 42 U.S.C. 9846.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–17871 Filed 8–19–19; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

[OMB#0985–XXXX]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adult Protective Services Client Outcome Study

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a 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 Proposed new information collection and solicits comments on the information collection requirements related to the ''Adult Protective Services Client Outcome Study''.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by October 21, 2019.

ADDRESSES: Submit electronic comments on the collection of information to: Stephanie Whittier Eliason. Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201, Attention: Stephanie Whittier Eliason.

FOR FURTHER INFORMATION CONTACT: Stephanie Whittier Eliason, Administration for Community Living, Washington, DC 20201, (202) 795–7467, *Stephanie.WhittierEliason@acl.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, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the

proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(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.

Description: The Administration for Community Living (ACL) in the U.S. Department of Health and Human Services (HHS) is seeking OMB approval to collect data using new information collection tools that examine if and how APS programs make a difference in the lives of APS clients. APS programs are provided by state and local governments nationwide and serve older adults and adults with disabilities in need of assistance due to maltreatment, which can include: Physical, emotional, and sexual abuse; financial exploitation; neglect; and self-neglect. APS is an important avenue through which maltreatment is reported to law enforcement or other agencies.

Additionally, APS programs are often the gateway for adults who experience maltreatment to access additional community, social, health, behavioral health, and legal services to maintain independence in the settings in which they prefer to live. APS programs work closely with clients and a wide variety of allied professionals to maximize safety and independence, while respecting each client's right to self-determination. At this time, there is no single funding stream for APS nor a single set of rules and regulations that APS programs must follow. Building the evidence-base for APS programs and practices, promoting the use of evidence-based and promising practices, and developing guiding standards are key needs for the APS field. The proposed new data collection is an important component for building the evidence-base for APS programs and practices in improving client outcomes.

Specifically, the data collection will help examine (1) what changes clients report as a result of receiving APS services; (2) how satisfied clients are with the APS services they receive; (3) to what extent clients report APS helps them achieve their goals; (4) to what extent clients report APS supports their right to self-determination; (5) to what extent APS programs affect client safety (risk of maltreatment); (6) how APS program intervene to reduce client risk of maltreatment; (7) what factors help or hinder APS efforts to reduce risk of maltreatment; (8) to what extent APS programs affect client well-being (*e.g.,* quality of life, financial, physical health, etc.); (9) how APS programs intervene to improve client-well-being; and (10) what factors help or hinder APS efforts to improve client well-being. The data collection will be conducted with three target populations: (1) APS clients, (2) APS caseworkers, and (3) APS leaders. APS leaders will consist of APS state and APS county leaders.

Data collection with these three target populations will include: A brief, anonymous APS client questionnaire, including a de-identified client data form; a semi-structured in-person interview with APS clients; a semi-structured in-person focus group with APS caseworkers; and a semi-structured interview with APS leaders.

The APS client questionnaire is designed to be as brief as possible, while examining key client outcome areas, identified in collaboration with a national expert panel consisting of federal experts, researchers, practitioners, and program leaders in APS. The outcomes areas focus on: Satisfaction with APS, safety, and well-being, and will be assessed with nine questions. The question statements examining these areas are designed to be short and easy to understand. The first item on the questionnaire provides a simple ''yes/no'' response option. For the remaining questions, APS clients or a proxy (respondents) are asked to rate the extent which they agree with each statement using a Likert-type rating scale ranging from 'strongly disagree' to 'strongly agree'. Respondents also have the option of sharing anything else about their experience with APS through an open-ended question at the end of the form. The questionnaire will be hand-delivered to the client or proxy respondent by the APS caseworker at case closure. The respondent will complete the questionnaire and mail it back to the research team by using a prepaid return envelope.

The client data form will be linked to the client questionnaire using a pre-populated eight-digit form number. The client data form is designed to capture de-identified, basic demographic information and additional details about APS clients and their cases.

These data points are expected to be among the information about clients, and their cases, that caseworkers already collect during normal APS processes. The form does not collect any personally identifiable information. The form will be completed online by APS caseworkers. If an APS program prefers another method of completing the form, hard copies can be provided and mailed back to the research team using a prepaid return envelope.

Individual interviews with APS clients are designed to gain more in-depth knowledge about the experiences and needs of APS clients along the key outcome areas assessed in the questionnaire. A standardized, semi-structured interview guide will be used to guide the interviews with clients who provide informed consent. Focus groups with APS caseworkers will be conducted in person, using a standardized, semi-structured focus group guide. Individual interviews with APS leaders will be conducted either in-person or by phone with county and state leaders using a standardized, semi-structured, interview guide. Similar to client interviews, focus groups with APS caseworkers and interviews with APS leaders will focus on the identified outcome areas. Additional questions will be asked to gain insight into access and availability of services, collaboration and partnerships with other entities in the community, and barriers and facilitating factors that affect APS services and client outcomes. The interview guide for APS leaders also contains questions related to APS polices and procedures.

The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Client Questionnaire	6,000	1	0.167	1,002
Client Data Form	6,000	1	0.167	1,002
Client Interview	24	1	0.75	18

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
APS Caseworker Focus Group	84	1	1.5	126
APS Leaders Interview	16	1	1	16
Total	12,124		3.58	2,164

Dated: August 14, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–17879 Filed 8–19–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0411]

Bristol-Myers Squibb Co. et al.; Withdrawal of Approval of 70 New Drug Applications and 97 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 8, 2011. The document announced the withdrawal of approval of 70 new drug applications (NDAs) and 97 abbreviated new drug applications from multiple applicants, effective July 8, 2011. The document contained the incorrect applicant information for NDA 018380. The correct applicant for NDA 018380 is Hospira, Inc. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, June 8, 2011 (76 FR 33310), appearing on page 33310 in FR Doc. 2011–14164, the following correction is made:

On page 33311, in table 1, in the ''Applicant'' column for NDA 018380, correct the entry ''Do.'' to read ''Hospira, Inc., 275 North Field Dr., Bldg. H2, Lake Forest, IL 60045–5046.''

Dated: August 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17933 Filed 8–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3500]

Fit for Use Pilot Program Invitation for the Clinical Data Interchange Standards Consortium for Standard for Exchange of Nonclinical Data Implementation Guide: Version 3.1

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it intends to conduct a Fit for Use (FFU) pilot program to test the processing and analysis of nonclinical study data provided electronically for the Clinical Data Interchange Standards Consortium (CDISC) for Standard for Exchange of Nonclinical Data (SEND) Implementation Guide (IG): Version 3.1 (SEND 3.1). The Agency's Center for Drug Evaluation and Research (CDER) will test the processing and analysis of nonclinical study data provided electronically in SEND 3.1 format. FDA is inviting individual firms that wish to participate in this pilot program to submit participation requests via email or in writing.

DATES: To be considered for participation in the pilot program, submit electronic or written requests by September 19, 2019. See the **ADDRESSES** section for participation request instructions.

ADDRESSES: Submit electronic requests to participate in the pilot and comments regarding this pilot project to *https://www.regulations.gov.* Submit written requests to participate in the pilot and comments regarding the pilot to Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time by September 19, 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–2019–N–3500 for ''Fit for Use Pilot Program Invitation for the Clinical Data Interchange Standards Consortium for Standard for Exchange of Nonclinical Data Implementation Guide: Version 3.1.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will