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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Gretchen Opper, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV–I/II); Draft Guidance for Industry.'' The draft guidance provides blood establishments that collect Whole Blood and blood components with recommendations for a requalification method under 21 CFR 610.41(b) for deferred donors, based on a determination that their previous reactive test results for anti-HTLV–I/II were falsely positive. Blood establishments are not required to test Source Plasma for HLTV I/II (21 CFR 610.40 (a)(2)(ii)). Therefore, this guidance does not apply to the collection of Source Plasma.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on recommendations for requalification of blood donors deferred because of reactive test results for antibodies to human T-lymphotropic virus types I and II (anti-HTLV–I/II). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 601 and Form FDA 356h have been approved under OMB control number 0910–0338, and the collections of information in 21 CFR parts 610 and 606 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: September 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20775 Filed 9–24–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0016]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before October 25, 2018.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 4040–0016–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collections: INSTRUCTIONS FOR THE SF–429 Real Property Status Report, SF–429 Real Property Status Report (Cover Page), SF–429–A Real Property Status Report ATTACHMENT A (General Reporting), SF–429–B Real Property Status Report ATTACHMENT B (Request to Acquire, Improve or Furnish), and SF–429–C Real Property Status Report ATTACHMENT C (Disposition or Encumbrance Request) forms.

Type of Collection: Extension.

OMB No.: 4040–0016.

Abstract: INSTRUCTIONS FOR THE SF–429 Real Property Status Report, SF–429 Real Property Status Report (Cover Page), SF–429–A Real Property Status Report ATTACHMENT A (General Reporting), SF–429–B Real Property Status Report ATTACHMENT B (Request to Acquire, Improve or Furnish), and SF–429–C Real Property Status Report ATTACHMENT C (Disposition or Encumbrance Request) forms are OMB-approved collections (4040–0016). These information collections are used by grant awardees to report on their grant award . The ICs expire on January 31, 2019. We are requesting a three-year clearance of these collections.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
INSTRUCTIONS FOR THE:				
SF–429 Real Property Status Report	100,000	1	0.5	50,000
SF–429 Real Property Status Report (Cover Page)	100,000	1	1	100,000
SF–429–A Real Property Status Report—ATTACHMENT A	100,000	1	1	100,000
SF–429–B Real Property Status Report—ATTACHMENT B (Request to Acquire, Improve or Furnish)	100,000	1	1	100,000
SF–429–C Real Property Status Report—ATTACHMENT C (Disposition or Encumbrance Request)	100,000	1	1	100,000
Total	500,000			450,000

Terry Clark,

Asst. Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2018–20815 Filed 9–24–18; 8:45 am]

BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Proposed Information Collection: Indian Health Service Purchased/Referred Care Proof of Residency

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) is submitting to the Office of Management and Budget (OMB) a request for approval of a new collection of information titled, ''Purchased/Referred Care Proof of Residency'' (OMB Control Number 0917–XXXX). This proposed information collection project was recently published in the **Federal Register** (83 FR 13764) on March 30, 2018, and allowed 60 days for public comment. The IHS received one comment regarding this collection. The question summary and response is listed in the notice. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

A copy of the draft supporting statement is available at *www.regulations.gov* (see Docket ID IHS_FRDOC_0001).

DATES: October 25, 2018. Your comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Direct Your Comments to OMB: Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

Public Comments: The Agency received one comment.

Comment: The commenter asked for clarification of the Proof of Residency form, to whom it would apply and requested a copy of the data collection instrument and instruction.

Response: The Proof of Residency form, IHS–976, is a Federal form applicable to only Federal Purchased/Referred Care (PRC) programs. For Tribes operating under Title I contracts or Title V compacts in accordance with Indian Self-Determination Education Assistance Act (ISDEAA) the IHS–976 is an optional use. Tribes may adopt usage of the form but all OMB text and the OMB Burden Statement should be removed. The form is developed to document residency within a PRC delivery area. The PRC eligibility requires residency documentation and the form will be used during the process of a PRC eligibility determination. The form is included in the IHS Indian Health Manual Part 2, Chapter 3, Purchased/Referred Care Manual. On May 23, IHS initiated Tribal Consultation per the ISDEAA for the manual.

SUPPLEMENTARY INFORMATION: The IHS Office of Resource Access and Partnerships/Division of Contract Care is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995.

This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques of other forms of information technology, *e.g.,* permitting electronic submission of responses.

Proposed Collection: Title: 0917–XXXX, ''Indian Health Service Purchased/Referred Care Proof of Residency.''

Type of Information Collection Request: This is a new information request for a three year approval of this new information collection, 0917–XXXX.

Forms: Purchase/Referred Care Proof of Residency Form.

OMB Control Number: To be assigned.

Need and Use of Information Collection: The IHS PRC Program needs this information to certify that the health care services requested and authorized by the IHS have been provided to individuals who are documented to meet the eligibility requirements to receive medical services from PRC provider(s); and to serve as a legal document for health and medical care authorized by IHS and rendered by health care providers under contract with the IHS.

Agency Form Number: ''None''.

Members of Affected Public: Patients.

Status of the Proposed Information Collection: New request.

Type of Respondents: Individuals.

The table below provides: Types of data collection instruments; estimation to number of respondents, number of responses per respondent, annual number of responses, average burden hour per response, and total annual burden hours.