This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on recommendations for requalification of blood donors deferred because of reactive test results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Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.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]
INSTRUCTIONS FOR THE:

<table>
<thead>
<tr>
<th>Forms</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF–429 Real Property Status Report</td>
<td>1</td>
<td>0.5</td>
<td>50,000</td>
</tr>
<tr>
<td>SF–429 Real Property Status Report (Cover Page)</td>
<td>1</td>
<td>1</td>
<td>100,000</td>
</tr>
<tr>
<td>SF–429–A Real Property Status Report—ATTACHMENT A</td>
<td>1</td>
<td>1</td>
<td>100,000</td>
</tr>
<tr>
<td>SF–429–B Real Property Status Report—ATTACHMENT B</td>
<td>1</td>
<td>1</td>
<td>100,000</td>
</tr>
<tr>
<td>SF–429–C Real Property Status Report—ATTACHMENT C (Disposition or Encumbrance Request)</td>
<td>1</td>
<td>1</td>
<td>100,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>500,000</strong></td>
<td><strong>1</strong></td>
<td><strong>450,000</strong></td>
</tr>
</tbody>
</table>

**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:**

**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. May 23, 2017 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.