

on the process for updating ANDA labeling after approval of the NDA for the RLD has been withdrawn. 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.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.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 § 314.94(a)(8) and 21 CFR 314.97 have been approved under OMB Control No. 0910–0001.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–0221–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0990–0221, scheduled to expire on September 30, 2016. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before August 10, 2016.

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

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, Information.CollectionClearance@hhs.gov or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0990–0221 and document identifier HHS–OS–0990–0221–30D for reference.

Information Collection Request Title: Family Planning Annual Report: Forms and Instructions.

Abstract: The Office of Population Affairs within the Office of the Assistant Secretary for Health seeks to renew the currently approved Family Planning Annual Report (FPAR) data collection and reporting tool (OMB No. 0990–0221). This annual reporting requirement is for family planning services delivery projects authorized and funded by the title X Family Planning Program [“Population Research and Voluntary Family Planning Programs” (Pub. L. 91–572)], which was enacted in 1970 as title X of the Public Health Service Act (section 1001; 42 U.S.C. 300). The FPAR data collection and reporting tool remains unchanged in this request to renew OMB approval to collect essential, annual data from title X grantees.

Likely Respondents: Respondents for this annual reporting requirement are centers that receive funding directly from OPA for family planning services authorized and funded under the title X Family Planning Program [“Population Research and Voluntary Family Planning Programs” (Pub. L. 91–572)], which was enacted in 1970 as title X of the Public Health Service Act (section 1001 of title X of the Public Health Service Act, 42 United States Code [U.S.C.] 300).

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average annualized burden per response (hours)	Annualized total burden (hours)
Grantees	FPAR	93 grantees	1	36	3,348
Totals	93	3,348

Terry S. Clark,

Asst. Information Collection Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Proposed Information Collection: Indian Health Service Medical Staff Credentials and Privileges Files

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 which requires 30 days for public comment on proposed information collection projects, the Indian Health Service (IHS) is submitting to the Office of Management and Budget (OMB) a request for an extension of a previously approved collection of information titled, “Indian Health Service Medical Staff Credentials and Privileges Files,” OMB Control Number 0917–0009, which expires August 31, 2016. This