172,200 prescription orders for compounded drugs ("total annual disclosures" in table 1, line 1). We estimate that the consultation between the compounding pharmacist and the prescriber and adding a notation to each prescription that does not already document this determination will take approximately 2 minutes per prescription order.

In addition, if the drug was compounded because the approved product was not commercially available because it was on the FDA drug shortage list, the prescription or a notation on the prescription should note that it was on the drug shortage list and the date the list was checked. We estimate that a total of approximately 6,888 compounders ("number of respondents" in table 1, line 2) will document this information on approximately 344,400 prescription orders for compounded drugs ("total annual disclosures" in table 1, line 2). We estimate that checking FDA’s drug shortage list and documenting this information will take approximately 2 minutes per prescription order.

Compounders under section 503A should maintain records of the frequency in which they have compounded drug products that are essentially copies of commercially available drug products and the number of prescriptions that they have filled for compounded drug products that are essentially copies of commercially available drug products to document that such compounding has not been done “regularly” or in “inordinate amounts.” We estimate that a total of approximately 3,444 compounders ("number of recordkeepers" in table 1) will keep approximately 165,312 records ("total annual records"). We estimate that maintaining the records will take approximately 2 minutes per record.

A licensed pharmacist or physician seeking to compound a drug product under section 503A should also maintain records of prescriptions for identified individual patients including notations that a prescriber has determined that the compounded drug has a change that produces a significant difference for the identified patient. The notification will take approximately 3 minutes per prescription.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Leslie Kux, Associate Commissioner for Policy.

[Docket No. FDA–2016–D–1673]

Updating Abbreviated New Drug Application Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHSS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn." This draft guidance describes a process for updating labeling for abbreviated new drug applications (ANDAs) in cases where FDA has withdrawn approval of the new drug application (NDA) for the ANDA’s reference listed drug (RLD) for reasons other than safety or effectiveness. The process described in this guidance is intended to complement existing Agency authorities and processes.

DATES: Although you can comment on any guidance at any time (see 21 CFR...
I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn.” This draft guidance describes a process for updating labeling for ANDAs in cases where FDA has withdrawn approval of the NDA for the ANDA’s RLD for reasons other than safety or effectiveness.

A generic drug is required to have the same labeling as the RLD at the time of approval, except for changes required because of differences approved under a suitability petition (see section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and § 314.93) or because the generic drug and the RLD are “produced or distributed by different manufacturers” (see section 505(j)(2)(A)(v) of the FD&C Act and § 314.94(a)(8)(iv) (21 CFR 314.94(a)(8)(iv))). As a general matter, all holders of marketing applications for drug products have an ongoing obligation to ensure their product labeling is accurate, and not false or misleading. ANDA holders are expected to update their labeling after FDA has approved relevant changes to the labeling for the corresponding NDA RLD.

Where approval of an NDA RLD has been withdrawn, the NDA holder can no longer update labeling for the withdrawn RLD. The labeling of ANDAs that rely on the withdrawn RLD might eventually become inaccurate and outdated, resulting in labeling that is false and/or misleading, for example. Likewise, new original ANDAs that rely on the withdrawn RLD might include proposed labeling based on the last approved RLD labeling that includes outdated information that is false and/or misleading. This draft guidance clarifies that consistent with the statute, where the RLD is withdrawn, certain labeling changes may continue to be made for pending ANDAs and marketed ANDAs. This draft guidance sets forth a process for making such changes. The process described in this guidance is intended to complement existing Agency authorities and processes.

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 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.

[FR Doc. 2016–16157 Filed 7–8–16; 8:45 am]

BILLING CODE 4150–34–P

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**


**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.Collection Clearance@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**

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Terry S. Clark,
Asst. Information Collection Clearance Officer.

[FR Doc. 2016–16300 Filed 7–8–16; 8:45 am]

BILLING CODE 4150–34–P

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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