172,200 prescription orders for compounded drugs (''total annual disclosures'' in table 1, line 1). We estimate that the consultation between the compounder and the prescriber and adding a notation to each prescription that does not already document this determination will take approximately 3 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. Because the time, effort, and financial resources necessary to comply with this collection of information would be incurred by licensed pharmacists and licensed physicians in the normal course of their activities, it is excluded from the definition of ''burden'' under 5 CFR 1320.3(b)(2). FDA understands that maintaining records of prescriptions for compounded drug products is part of the usual course of the practice of compounding and selling drugs and is required by States' pharmacy laws and other state laws governing recordkeeping by health care professionals and health care facilities.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| Type of reporting | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| Consultation between the compounder and prescriber and the notation on the prescription documenting the prescriber's determination of significant difference. | 6,888 | 50 | 344,400 | 3 minutes ..... | 17,220 |
| Checking FDA's drug shortage list and documenting on the prescription that the drug is in shortage. | 6,888 | 50 | 344,400 | 2 minutes ..... | 11,480 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Type of recordkeeping | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Records of frequency and number of prescriptions filled for compounded drugs that are essentially a copy. | 3,444 | 48 | 165,312 | 2 minutes ..... | 5,510 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

## 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.*

Dated: July 6, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–16361 Filed 7–8–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[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, HHS.

**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

10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 9, 2016.

**ADDRESSES:** You may submit comments as follows:

**Electronic Submissions**

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–1673 for ''Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Emily Helms Williams, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3381, *emily.helmswilliams@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

**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 21 CFR 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 4164–01–P**

## 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.*

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

**BILLING CODE 4150–34–P**

## 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