*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 guidances 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance documents.

**FOR FURTHER INFORMATION CONTACT:** Wendy Good, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 240–402–1146.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on February 25, 2019 (84 FR 6005). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

## II. Drug Products For Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

| |
|---|
| Acetaminophen; Codeine phosphate |
| Apalutamide |
| Beclomethasone dipropionate |
| Benoxinate hydrochloride; Fluorescein sodium |
| Bictegravir sodium; Emtricitabine; Tenofovir alafenamide fumarate |
| Brimonidine tartrate |
| Budesonide |
| Chlorpheniramine maleate; Ibuprofen; Pseudoephedrine hydrochloride |
| Cyclosporine |
| Desloratadine; Pseudoephedrine sulfate |
| Desmopressin acetate |
| Efavirenz; Lamivudine; Tenofovir disoproxil fumarate (multiple Reference Listed Drugs) |
| Eravacycline dihydrochloride |
| Estradiol; levonorgestrel |
| Fluticasone furoate |
| Fluticasone propionate |
| Fluticasone propionate; Salmeterol xinafoate |
| Fosnetupitant chloride hydrochloride; Palonosetron hydrochloride |
| Halcinonide |
| Lamivudine; Tenofovir disoproxil fumarate |
| Naproxen |
| Omeprazole magnesium |
| Primidone |
| Timolol maleate |
| Tobramycin |

## III. Drug Products for Which Revised Draft Product-Specific Guidances are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

| |
|---|
| Azelaic acid (multiple Reference Listed Drugs) |
| Betaxolol hydrochloride |
| Brimonidine tartrate; Brinzolamide |
| Brinzolamide |
| Fosfomycin tromethamine |
| Ivermectin |
| Methylprednisolone |
| Prednisolone acetate |
| Tofacitinib citrate |

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. These guidances are not subject to Executive Order 12866.

## IV. Electronic Access

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

Dated: May 13, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–10165 Filed 5–15–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0990–0458 Revision]**

### Agency Information Collection Request; 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) 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 revision of a collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 17, 2019.

**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 OS–0990–0458 Revision, 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 Collection:* Domestic Violence Housing First Demonstration Evaluation.

*Type of Collection:* Revision.

*OMB No.:* 0990–0458.

*Abstract:* The Office of the Assistant Secretary for Planning and Evaluation (ASPE) within the U.S. Department of Health and Human Services, in partnership with the Office for Victims of Crimes within the U.S. Department of Justice, is seeking approval by OMB for a revision to add a 24-month follow-up data collection to an existing information collection request entitled, ''Domestic Violence Housing First (DVHF) Demonstration Evaluation'' (OMB Control Number: HHS–OS–0990–0458). The Washington State Coalition against Domestic Violence (WSCADV) is overseeing and coordinating an evaluation of the DVHF Demonstration project through a contract with ASPE. This quasi-experimental research study involves longitudinally examining the program effects of DVHF on domestic violence survivors' safety and housing stability. The findings will be of interest to the general public, to policy-makers, and to organizations working with domestic violence survivors.

Current data collection that has been approved by OMB includes in-depth, private interviews with 320 domestic violence survivors conducted by trained professional staff. The data are currently approved for collection at study enrollment (Time 1), and at follow-up interviews every six months after the Time 1 Interview (*i.e.,* 6, 12, and 18 months) to examine the match between needs and services, as well as their safety and housing stability. The proposed revision to the collection would add a fourth follow-up data collection to be administered 24 months after study enrollment (Time 1) to examine longer-term impacts of the Domestic Violence Housing First Demonstration program. The follow-up survey is identical to the one used at the 6, 12, and 18 month follow-up. The respondents are domestic violence survivors who are enrolled in the Domestic Violence Housing First Demonstration Evaluation (OMB Control Number HHS–OS–0990–0458). Study enrollment is taking place over 15 months, so the annualized burden for the 24-month follow-up survey is based on 12/15 (256) of the expected sample (320).

ANNUALIZED BURDEN HOUR TABLE

| Form name | Type of respondent | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Total annual burden hours |
|---|---|---|---|---|---|
| Follow-up Interview | Domestic violence survivors | 256 | 1 | 1.25 | 320 |
| Total | | | | | 320 |

Dated: May 8, 2019.

**Terry Clark,**

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

[FR Doc. 2019–10107 Filed 5–15–19; 8:45 am]

**BILLING CODE 4150–05–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

### American Indians Into Psychology

*Announcement Type:* New and Competing Continuation.

*Funding Announcement Number:* HHS–2019–IHS–INPSY–0001.

*Assistance Listing (Catalog of Federal Domestic Assistance) Number:* 93.970.

**Key Dates**

*Application Deadline Date:* June 20, 2019.

*Earliest Anticipated Start Date:* July 20, 2019.

**I. Funding Opportunity Description**

*Statutory Authority*

The Indian Health Service (IHS) Division of Health Professions Support, is accepting applications for cooperative agreements for American Indians into Psychology. This program is authorized under section 217 of the Indian Health Care Improvement Act, Public Law 94–437, as amended (IHCIA), codified at 25 U.S.C. 1621p. This program is described in the Assistance Listings located at *https://beta.sam.gov* (formerly known as Catalog of Federal Domestic Assistance) under 93.970.

*Background*

The IHS, an agency within the Department of Health and Human Services (HHS), is responsible for providing Federal health services to American Indians and Alaska Natives (AI/AN). The mission of the IHS is to raise the physical, mental, social, and spiritual health of AI/AN. The IHCIA authorizes the IHS to administer programs that are designed to attract and recruit qualified individuals into health professions to ensure the availability of health professionals to serve AI/AN populations. Section 217 of the IHCIA authorizes IHS to administer the American Indians into Psychology Program. Within the Section 217 program, IHS provides grants to colleges and universities to develop and maintain psychology education programs and recruit individuals to become Clinical Psychologists who will provide services to AI/AN people. Psychology program scholarship grants may be used by the educational institution to provide scholarships to Indian students enrolled in clinical psychology education programs. According to the terms and conditions of the psychology program scholarship grant award, scholarship awards are for a l-year period; additional scholarship support may be awarded to each eligible student for up to four years (maximum).

*Purpose*

The purpose of this IHS cooperative agreement is to augment the number of Indian Clinical Psychologists who deliver health care services to AI/AN communities. The primary objectives of this cooperative agreement award are to: (1) Recruit and train individuals to be Clinical Psychologists; and (2) provide scholarships to individuals enrolled in schools of clinical psychology to pay tuition, books, fees and stipends for living expenses.

**II. Award Information**

*Funding Instrument*

Cooperative Agreement.