

chlorthalidone USP tablets, 15 mg, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Christopher Koepke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6214, Silver Spring, MD 20993-0002, 240-402-3543.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

THALITONE (chlorthalidone USP) tablets, 15 mg, are the subject of NDA 19-574, held by Citron Pharma LLC, and initially approved on December 20, 1988. THALITONE is indicated for the management of hypertension either alone or in combination with other antihypertensive drugs. Chlorthalidone is indicated as an adjunctive therapy in edema associated with congestive heart

failure, hepatic cirrhosis, and corticosteroid and estrogen therapy. Chlorthalidone has also been found useful in edema due to various forms of renal dysfunction such as nephrotic syndrome, acute glomerulonephritis, and chronic renal failure.

THALITONE (chlorthalidone USP) tablets, 15 mg, are currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Clinipace Worldwide submitted a citizen petition dated September 9, 2015 (Docket No. FDA-2015-P-3299), under 21 CFR 10.30, requesting that the Agency determine whether THALITONE (chlorthalidone USP) tablets, 15 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information, FDA has determined under § 314.161 that THALITONE (chlorthalidone USP) tablets, 15 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that THALITONE (chlorthalidone USP) tablets, 15 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of THALITONE (chlorthalidone USP) tablets, 15 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list THALITONE (chlorthalidone USP) tablets, 15 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to THALITONE (chlorthalidone USP) tablets, 15 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 19, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Request for Public Comment: 60-Day Information Collection: Indian Self-Determination and Education Assistance Act Contracts

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice and request for comments. Request for extension of approval.

**SUMMARY:** In compliance the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on the information collection titled, "Indian Self-Determination and Education Assistance Act Contracts," Office of Management and Budget (OMB) Control Number 0917-0037. IHS is requesting OMB to approve an extension for this collection, which expires on July 31, 2016.

**DATES:** *Comment Due Date:* June 24, 2016. Your comments regarding this information collection are best assured of having full effect if received within 60 days of the date of this publication.

**ADDRESSES:** Send your written comments, requests for more information on the collection, or requests to obtain a copy of the data collection instrument and instructions to Mr. Chris Buchanan by one of the following methods:

- *Mail:* Mr. Chris Buchanan, Director, IHS Office of Direct Services and Contracting Tribes (ODSCT), Indian Health Service, 5600 Fishers Lane, Mail Stop O8E17C, Rockville, MD 20857.
- *Phone:* 301-443-1104.
- *Email:* [Chris.Buchanan@ihs.gov](mailto:Chris.Buchanan@ihs.gov).
- *Fax:* 301-480-3192.

**SUPPLEMENTARY INFORMATION:** This previously approved information collection project was last published in the **Federal Register** (78 FR 32405), as a joint submission with the Bureau of Indian Affairs (BIA), under OMB Control Number 1076-0136, on May 30, 2013 and allowed 30 days for public comment. No public comment was received in response to the notice. On July 31, 2013, the IHS obtained its own OMB Control Number, 0917-0037, for this information collection and is now publishing a separate notice from the BIA in the **Federal Register**. The purpose of this notice is to allow 60 days for public comment. A copy of the supporting statement is available at [www.regulations.gov](http://www.regulations.gov) (see Docket ID IHS-2016-0003).

## I. Abstract

Representatives of the IHS seek renewal of the approval for information collections conducted under 25 CFR part 900, implementing the Indian Self-Determination and Education Assistance Act (ISDEAA), as amended (25 U.S.C. 450 *et seq.*), which describes how contracts are awarded to Indian Tribes. The rule at 25 CFR part 900 was developed through negotiated rulemaking with Tribes in 1996 and governs, among other things, what must be included in a Tribe's initial ISDEAA contract proposal to IHS. A response is required to obtain and retain a benefit.

The information requirements for this rule represent significant differences from other agencies in several respects. Under the Act, the Secretary of Health and Human Services is directed to enter into self-determination contracts with Tribes upon request, unless specific declination criteria apply, and, generally, Tribes may renew these contracts annually, whereas other agencies provide grants on a discretionary or competitive basis. Additionally, IHS awards contracts for multiple programs whereas other agencies usually award single grants to Tribes.

The IHS uses the information collected to determine applicant eligibility, evaluate applicant capabilities, protect the service population, safeguard Federal funds and other resources, and permit the Federal agency to administer and evaluate contract programs. Tribal governments or Tribal organizations provide the information by submitting contract proposals, and related information, to the IHS, as required under Public Law 93-638. No third party notification or public disclosure burden is associated with this collection.

## II. Request for Comments

The IHS requests your comments on this collection concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of

information unless it displays a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. Before including your address, phone number, email address or other personally identifiable information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

## III. Data

*OMB Control Number:* 0917-0037.

*Title:* Indian Self-Determination and Education Assistance Act Contracts, 25 CFR part 900.

*Brief Description of Collection:* An Indian Tribe or Tribal organization is required to submit this information each time that it proposes to contract with the IHS under the ISDEAA. Each response may vary in its length. In addition, each subpart of 25 CFR part 900 concerns different parts of the contracting process. For example, subpart C relates to provisions of the contents for the initial contract proposal. The respondents do not incur the burden associated with subpart C when contracts are renewed. Subpart F describes minimum standards for management systems used by Indian Tribes or Tribal organizations under these contracts. Subpart G addresses the negotiability of all reporting and data requirements in the contracts. Responses are required to obtain or retain a benefit.

*Type of Review:* Revision of currently approved collection.

*Respondents:* Federally recognized Indian Tribes and Tribal organizations.

*Number of Respondents:* 566.

*Estimated Number of Responses:* 1510.

*Estimated Time per Response:* Varies from 1 to 1040 hours, with an average of 15.968 hours per response.

*Frequency of Response:* Each time programs, functions, services or activities are contracted from the IHS under the ISDEAA.

*Estimated Total Annual Hour Burden:* 24,112.

Dated: April 18, 2016.

**Elizabeth A. Fowler,**

*Deputy Director For Management Operations, Indian Health Service.*

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**BILLING CODE 4165-16-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director, National Institutes of Health Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Advisory Committee to the Director, National Institutes of Health.

*Date:* June 9-10, 2016.

*Time:* June 09, 2016, 9:00 a.m. to 5:00 p.m.

*Agenda:* NIH Director's Report, ACD Working Group reports.

*Place:* National Institutes of Health Building 31, 6th Floor Conference Room 6C6, 31 Center Drive, Bethesda, MD 20892.

*Time:* June 10, 2016, 9:00 a.m. to adjournment

*Agenda:* IC Director Report and other business of the committee.

*Place:* National Institutes of Health, Building 31, 6th Floor Conference Room 6C6, 31 Center Drive, Bethesda, MD 20892.

*Contact Person:* Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301-496-4272, [woodgs@od.nih.gov](mailto:woodgs@od.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://acd.od.nih.gov>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired