ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Procedures for Requests from Tribal Lead Agencies to use Child Care and Development Fund (CCDF) Funds for Construction or Major Renovation of Child Care Facilities (for all tribes)	50	1	20	1000

Estimated Total Annual Burden Hours: 1,000

Authority: 42 U.S.C. 9858(c)(6)

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–17167 Filed 8–9–19; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Public Comment Request; State Plan for Independent Living Instrument and Instructions OMB Control Number 0985–0044

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This Proposed Revision of a Currently Approved Collection (ICR Rev) solicits comments on the information collection requirements related to the State Plan for Independent Living.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by October 11, 2019.

ADDRESSES: Submit electronic comments on the information collection request to: Peter Nye at *peter.nye@acl.hhs.gov.* Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201, Attention: Peter Nye.

FOR FURTHER INFORMATION CONTACT: Peter Nye, Administration for Community Living, Washington, DC 20201, (202) 795–7606, or *peter.nye@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor, including agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document. With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Legal authority for the State Plan for Independent Living (SPIL) is contained in Chapter 1 of Title VII of the Rehabilitation Act of 1973, as amended (the Act). Section 704 of the Rehabilitation Act requires that, to be eligible to receive financial assistance under Chapter 1, ''a State shall submit to the Department, and obtain approval of, a State plan containing such provisions as the Department may require.'' ACL approval of the SPIL is required for states to receive federal funding for both the Independent Living Services State grants and Centers for Independent Living (CIL) programs. Federal statute and regulations require the collection of this information every three years.

The SPIL is jointly developed by the chairperson of the Statewide Independent Living Council (SILC) and not less than 51% of the directors of the CILs, after receiving public input from individuals throughout the State. ACL reviews the SPIL for compliance with the Rehabilitation Act and its applicable regulations (Sec 704(a)(4); 45 CFR part 1329.17) and approves the SPIL. It serves statewide as a primary planning document that describe[s] strategies—including how, and to whom, the state will disburse what funds—for providing independent living services and designates the Designated State Entity. The SPIL also assures that all IL grantees in the state will comply with the Act's requirements. § 704(a)(5) of the Act; 45 CFR 1329.17(a–b), citing sec. 704(m) of the Act. The SPIL Instrument is the template for SPILs; the SPIL Instructions explain the Instrument and give tips about how to draft SPILs.

ACL is proposing this revision because ACL and the technical assistance provider have been revising the Instrument and Instructions to address changes to the Act that result from the Workforce Innovation and Opportunity Act of 2014, 29 U.S.C. 32, and to increase the Instrument's and Instructions' clarity, conciseness, and precision. For example,

- The revised Instrument and Instructions will reflect the core services that WIOA requires.
- The revised Instructions will explain the state matching requirement, and the revised Instrument will specify how to include the state match in the financial plan.
- The revised Instrument and Instructions will add legal basis and certifications and DSE assurances and SILC assurances.

• The Revised Instrument and Instructions will include a chart for the financial plan and a chart for the existing centers that specifies what counties they serve, what entities oversee them, and what oversight processes apply.

• The Revised Instrument will include a signatures section.

These revisions were recommended by the technical assistance provider and analyzed by all the independent living program officers who work directly with SPILs.

The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden associated with this collection of information as follows: 56 SILCs will respond to the requirement for a SPIL every three years. Each state's SILC will take approximately 240 hours to develop the SPIL for a total of approximately 13,440 hours. This estimate is based on program knowledge.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Statewide Independent Living Councils	56	1	240	13,440
Total	56	1	240	13,440

Dated: August 6, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–17172 Filed 8–9–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–2290]

Determination That LEVITRA (Vardenafil Hydrochloride) Tablets, 2.5 Milligrams Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that LEVITRA (vardenafil hydrochloride) tablets, 2.5 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Daniel J. Ritterbeck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 301–796–4673, *Daniel.Ritterbeck@fda.hhs.gov.*

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.

LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg, are the subject of NDA 021400, held by Bayer HealthCare Pharmaceuticals, Inc., and initially approved on August 19, 2003. LEVITRA is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction. LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

In a letter dated March 22, 2018, Bayer HealthCare Pharmaceuticals, Inc., notified FDA that LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg, were being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Alembic Pharmaceuticals Limited submitted a citizen petition received on May 9, 2019 (Docket No. FDA–2019–P–2290), under 21 CFR 10.30, requesting that the Agency determine whether LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg, were withdrawn from sale for safety or effectiveness reasons and permit the filing of abbreviated new drug applications (ANDAs) referencing LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LEVITRA (vardenafil hydrochloride) tablets, 2.5 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LEVITRA (vardenafil hydrochloride) tablets, 2.5 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