DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; Centers for Independent Living Program Performance Report (0985–NEW)

AGENCY: Administration for Community Living (ACL), HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to Centers for Independent Living Program Performance Report (New Data Collection (ICR New)).

DATES: Comments on the information collection request must be submitted electronically by 11:59 p.m. (EST) or postmarked by January 25, 2019.

ADDRESSES: Submit written comments on the collection of information by:

(a) email to: *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL;

(b) fax to 202.395.5806, Attn: OMB Desk Officer for ACL; or

(c) by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

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

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. The Act of 1973 requires three Independent Living program reports: (1) State Plan for Independent Living, (2) Independent Living Services (ILS) Program Performance Report (PPR), and (3) Centers for Independent Living (CIL) PPR. The ILS PPR and CIL PPR were previously combined into one submission. However, for the purposes of this data collection, the ILS PPR and CIL PPR are being submitted separately because they are separate collections of different information from different parties. This will result in a new OMB approval number for the CIL program. Separating these PRA processes reduces confusion and increases the Independent Living Administration's (ILA) ability to identify issues specific to DSEs and Statewide Independent Living Councils. This request is for the CIL PPR, which is submitted annually by all CILs receiving Subchapter C funds. The CIL PPRs are used by ACL to assess grantees' compliance with title VII of the Act, with 45 CFR part 1329 of the Code of Federal Regulations, and with applicable provisions of the HHS Regulations at 45 CFR part 75. The CIL PPR serves as the primary basis for ACL's monitoring activities in fulfillment of its responsibilities under sections 706 and 722 of the Act. The CIL PPR enables ACL to track performance outcomes and efficiency measures of the CIL programs with respect to the annual and long-term performance targets established in compliance with GPRA. The PPR is also used by ACL to design CIL and SILC training and technical assistance programs authorized by section 721 of the Act.

The current version of the CIL PPR that ILA is requesting an extension for was approved by OMB, but will expire on December 31, 2018. ILA plans to publish a revised CIL program data collection instrument before the expiration of the extension request.

Comments in Response to the 60-Day Federal Register Notice

A notice was published in the **Federal Register** on October 19, 2018 (Vol. 83, Number 2018–22754; pp. 53064–53065).

We received a comment that applied to this notice, as indicated below.

Data collection form	Comment	ACL Response
One commenter asked whether ACL has an update on the publication of the revised CIL indicators.	ACL has no update on the publication of the revised CIL indicators.	No change has been made.

The proposed form(s) may be found on the ACL website at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden

ACL estimates the burden of this collection of information as follows: 353 Centers for Independent Living will each complete one CIL PPR annually, and it will take an estimated 35 hours per CIL for an estimated total of 12,355 hours. This burden estimate is based partly on ILA's estimates of how long CILs take to find the information that PPRs ask for and partly on what CILs have told ILA about how long CILs spend filling out PPRs.

TABLE 37—RANGE TO EFFECTS (METERS) FROM AIR GUNS FOR 1 PULSE

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Centers for Independent Living	353	1	35	12,355
Total	353	1	35	12,355

Dated: December 18, 2018.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2018–27898 Filed 12–21–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–E–5040]

Determination of Regulatory Review Period for Purposes of Patent Extension; ADLYXIN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined the regulatory review period for ADLYXIN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 25, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 24, 2019. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 25, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 25, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2017–E–5040 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ADLYXIN.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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 § 10.20 (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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts