

Dated: October 17, 2017.

**Leroy A. Richardson,**  
*Chief, Information Collection Review Office,  
 Office of Scientific Integrity, Office of the  
 Associate Director for Science, Office of the  
 Director, Centers for Disease Control and  
 Prevention.*

[FR Doc. 2017-22893 Filed 10-20-17; 8:45 am]  
**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND  
 HUMAN SERVICES**

**Administration for Community Living**

**Agency Information Collection  
 Activities; Proposed Collection; Public  
 Comment Request; Revision of a  
 Currently Approved Information  
 Collection (ICR-Rev) (OMB Approval  
 Number 0985-0004); Maintenance of  
 Effort for Title III and Extension of, and  
 Minor Revisions Due to Statutory  
 Language Changes to the Certification  
 of Long-Term Care Ombudsman  
 Program Expenditures**

**AGENCY:** Administration for Community  
 Living, HHS.

**ACTION:** Notice.

**SUMMARY:** 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.  
 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

(the PRA). This 30-Day notice requests  
 comments on the information collection  
 requirements related to the proposed  
 revision of an existing data collection  
 regarding the information collection  
 requirements in the Maintenance of  
 Effort collection form for all ACL/AoA  
 Title III Grantees.

**DATES:** Submit written or electronic  
 comments on the collection of  
 information by November 22, 2017.

**ADDRESSES:** Submit written comments  
 on the collection of information: By fax  
 at 202.395.5806 or by email to *OIRA  
 submission@omb.eop.gov*, Attn: OMB  
 Desk Officer for ACL.

**FOR FURTHER INFORMATION CONTACT:**  
 Jesse Moore at (202) 795-7578 or  
*Jesse.Moore@acl.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In  
 compliance with Section 44 U.S.C.  
 3507, ACL has submitted the following  
 proposed collection of information to  
 OMB for review and clearance. ACL is  
 requesting approval for three years of an  
 extension of the currently approved data  
 collection with modifications.

The Certification of Maintenance of  
 Effort under Title III and Certification  
 of Long-Term Care Ombudsman (LTCO)  
 Program Expenditures provide  
 statutorily required information  
 regarding each state's contribution to  
 programs funded under the Older  
 Americans Act and compliance with  
 legislative requirements, pertinent  
 Federal regulations, and other  
 applicable instructions and guidelines  
 issued by ACL.

In addition to renewing OMB  
 approval of these data collection  
 instruments, minor changes are being  
 proposed to the LTCO Expenditures

Certification and an accompanying  
 document which provides specific  
 statutory references related to  
 Ombudsman program minimum  
 funding, non-supplanting requirements,  
 and state authorization to expend Title  
 III-B funds on Ombudsman activities.  
 Specifically, changes include making  
 the reference to the Fiscal Year at the  
 bottom of the form a fillable field to  
 allow the date to be changed annually;  
 listing the "Administration for  
 Community Living (ACL)" as the  
 intended recipient of the completed  
 form; and updating statutory language  
 references, *i.e.*, Section 306(a)(9), which  
 is provided on the second page, to  
 reflect changes made during the 2016  
 reauthorization of the OAA.

**Comments in Response to the 60-Day  
 Federal Register Notice**

A 60-Day notice was published in the  
**Federal Register** in Vol. 82, No. 137, on  
 June 19, 2017. No comments were  
 received.

**Annual Burden Estimates**

ACL estimates the burden of this  
 collection of information as follows: 56  
 State Agencies on Aging respond  
 annually, and it takes each agency an  
 average of one half (1/2) hour per State  
 agency per year to complete each form  
 for a total of twenty-eight hours for all  
 state agencies annually. The half hour  
 estimate is based on prior years'  
 experience with States in completing  
 these forms.

The proposed data collection tool may  
 be found on the ACL Web site for  
 review at: <https://www.acl.gov/about-acl/public-input>.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Certification on Maintenance of Effort under Title III .....	56	1/year .....	1/2	28
Certification of Long-Term Care Ombudsman Program Expenditures .....	56	1/year .....	1/2	28
<b>Total .....</b>	<b>112</b>	<b>2 .....</b>	<b>1</b>	<b>56</b>

Dated: October 12, 2017.

**Mary Lazare,**  
*Principal Deputy Administrator.*

[FR Doc. 2017-22914 Filed 10-20-17; 8:45 am]  
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**DEPARTMENT OF HEALTH AND  
 HUMAN SERVICES**

**Food and Drug Administration**

**[Docket Nos. FDA-2014-E-2358 and FDA-  
 2014-E-2359]**

**Determination of Regulatory Review  
 Period for Purposes of Patent  
 Extension; MITRACLIP CDS**

**AGENCY:** Food and Drug Administration,  
 HHS.

**ACTION:** Notice.

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

**DATES:** Anyone with knowledge that any  
 of the dates as published (in the

**SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by December 22, 2017. 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 April 23, 2018. 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 December 22, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 22, 2017. 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 Nos. FDA-2014-E-2358 and FDA-2014-E-2359 for “Determination of Regulatory Review Period for Purposes of Patent Extension; MITRACLIP CDS.” 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device MITRACLIP CDS. MITRACLIP CDS is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation. Subsequent to this approval, the USPTO received patent term restoration applications for MITRACLIP CDS (U.S.

Patent No. 7,288,097 from Abbott Vascular Inc., and U.S. Patent No. 7,464,712, from The Trustees of Columbia University in the City of New York), and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated November 2, 2015, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of MITRACLIP CDS represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

## II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for MITRACLIP CDS is 3,846 days. Of this time, 2,515 days occurred during the testing phase of the regulatory review period, while 1,331 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* April 16, 2003. FDA has verified the applicants' claims that the date the investigational device exemption required under section 520(g) of the FD&C Act for human tests to begin became effective was April 16, 2003.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* March 4, 2010. The applicants claim March 30, 2009, as the date the premarket approval application (PMA) for MITRACLIP CDS (PMA P100009) was initially submitted. However, FDA records indicate that the PMA submitted on March 30, 2009, was incomplete. The complete PMA was submitted on March 4, 2010, which is considered to be the PMA initially submitted date.

3. *The date the application was approved:* October 24, 2013. FDA has verified the applicants' claims that PMA P100009 was approved on October 24, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In the applications for patent extension, the applicants seek 1,827 days or 1,721 days of patent term extension.

## III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: October 17, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–22895 Filed 10–20–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2015–E–3529]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; Inspire Upper Airway Stimulation System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Inspire Upper Airway Stimulation System (Inspire UAS System) 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 medical device.

**DATES:** Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by December 22, 2017. 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 April 23, 2018. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

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