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 Tittle 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 (½) 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	½	28
Certification of Long-Term Care Ombudsman Program Expenditures	56	1/year	½	28
Total	112	2	1	56

Dated: October 12, 2017.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2017–22914 Filed 10–20–17; 8:45 am]

BILLING CODE 4154–01–P

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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- 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'').

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