

<http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 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 with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory

review period may count toward the actual amount of extension that the Director of USPTO may award (for example, 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 human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product ELIQUIS (apixaban). ELIQUIS is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. Subsequent to this approval, the USPTO received a patent term restoration application for ELIQUIS (U.S. Patent No. 6,967,208) from Bristol-Myers Squibb Company, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 27, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ELIQUIS 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 ELIQUIS is 3,685 days. Of this time, 3,227 days occurred during the testing phase of the regulatory review period, while 458 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:*

November 28, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 28, 2002.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* September 28, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for ELIQUIS (NDA 202155) was initially submitted on September 28, 2011.

3. *The date the application was approved:* December 28, 2012. FDA has verified the applicant's claim that NDA 202155 was approved on December 28, 2012.

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 its application for patent extension, this applicant seeks 1,424 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 ask for a redetermination (see **DATES**). 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. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (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 <http://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 4, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-31096 Filed 12-9-15; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2014-E-0271]

##### Determination of Regulatory Review Period for Purposes of Patent Extension; ARGUS II VISUAL STIMULATION SYSTEM

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for ARGUS II VISUAL STIMULATION 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 (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 8, 2016. 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 7, 2016. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2014-E-0271 for Determination of Regulatory Review Period for Purposes of Patent Extension; ARGUS II VISUAL STIMULATION SYSTEM. Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. 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 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>. For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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**SUPPLEMENTARY INFORMATION:**

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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 ARGUS II VISUAL STIMULATION SYSTEM. ARGUS II VISUAL STIMULATION SYSTEM is indicated for patients aged 25 years and older with bare or no light perception vision caused by advanced retinitis pigmentosa. Subsequent to this approval, the USPTO received a patent term restoration application for ARGUS II VISUAL STIMULATION SYSTEM (U.S. Patent No. 7,668,599) from Second Sight Medical Products, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 22, 2014, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of ARGUS II VISUAL STIMULATION SYSTEM 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 ARGUS II VISUAL STIMULATION SYSTEM is 2,282 days. Of this time, 1,630 days occurred during the testing phase of the regulatory review period, while 652 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:* November 17, 2006. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C act for human tests to begin became effective on December 31, 2004. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on November 17, 2006, which represents the IDE effective date.

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):* May 4, 2011. The applicant claims May 3, 2011, as the date the humanitarian device exemption (HDE) for Argus II Visual Stimulation System (HDE H110002) was initially submitted. However, FDA records indicate that HDE H110002 was submitted on May 4, 2011.

3. *The date the application was approved:* February 13, 2013. The applicant claims that HDE H110002 was approved on February 14, 2013. However, FDA records indicate that ARGUS II VISUAL STIMULATION SYSTEM was approved on February 13, 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 its application for patent extension, this applicant seeks 1,735 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 ask for a redetermination (see DATES). 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. To meet its burden, the petition must be timely (see DATES) and contain sufficient facts to merit an FDA

investigation. (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 <http://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 4, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–31095 Filed 12–9–15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2013–N–0093]

#### **Agency Information Collection Activities: Proposed Collection; Comment Request; Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Acts**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish 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 notice solicits comments on the information collection involving interviews of pharmaceutical manufacturers who submit new molecular entity (NME) new drug applications (NDAs) and original biologics license applications (BLAs) to FDA under the Program for Enhanced Review Transparency and Communication (the Program) during fiscal years (FYs) 2013–2017. The

Program is part of the FDA performance commitments under the fifth authorization of the Prescription Drug User Fee Act (PDUFA), which allows FDA to collect user fees for the review of human drug and biologics applications for FYs 2013–2017.

**DATES:** Submit either electronic or written comments on the collection of information by February 8, 2016.

**ADDRESSES:** You may submit comments as follows:

#### **Electronic Submissions**

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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–2013–N–0093] for “Agency Information Collection Activities: Proposed Collection; Comment Request; Evaluation of the Program for Enhanced Review Transparency and