

Furthermore, Presidential Policy Directive 21—Critical Infrastructure Security and Resilience (PPD–21) issued on February 12, 2013 tasks Federal Government entities to strengthen the security and resilience of critical infrastructure against physical and cyber threats such that these efforts reduce vulnerabilities, minimize consequences, and identify and disrupt threats. PPD–21 encourages all public and private stakeholders to share responsibility in achieving these outcomes.

In recognition of the shared responsibility for cybersecurity, the security industry has established resources including standards, guidelines, best practices and frameworks for stakeholders to adopt a culture of cybersecurity risk management. Best practices include collaboratively assessing cybersecurity intelligence information for risks to device functionality and clinical risk. FDA believes that, in alignment with Executive Order 13636 and PPD–21, public and private stakeholders should collaborate to leverage available resources and tools to establish a common understanding that assesses risks for identified vulnerabilities in medical devices among the information technology community, healthcare delivery organizations, the clinical user community, and the medical device community. These collaborations can lead to the consistent assessment and mitigation of cybersecurity threats, and their impact on medical device safety and effectiveness, ultimately reducing potential risk of patient harm.

Part 806 (21 CFR part 806) requires device manufacturers or importers to report promptly to FDA certain actions concerning device corrections and removals. However, the majority of actions taken by manufacturers to address cybersecurity vulnerabilities and exploits, referred to as “cybersecurity routine updates and patches,” are generally considered to be a type of device enhancement for which the FDA does not require advance notification or reporting under part 806. For a small subset of actions taken by manufacturers to correct device cybersecurity vulnerabilities and exploits that may pose a risk to health, the FDA would require medical device manufacturers to notify the Agency.

This guidance clarifies changes to devices to be considered cybersecurity routine updates and patches (*e.g.*, certain actions to maintain a controlled risk to health). In addition, the guidance outlines circumstances in which FDA does not intend to enforce reporting requirements under part 806 for specific

vulnerabilities with uncontrolled risk. Specifically, FDA does not intend to enforce the reporting requirements when circumstances outlined in the guidance are met within the predefined periods of time (*e.g.*, communicate vulnerability to customers and user community and propose a timeline for remediation within 30 days after learning of the vulnerability; fix the vulnerability and validate the change within 60 days after learning of the vulnerability; actively participate in an Information Sharing Analysis Organization (ISAO)). The Agency considers voluntary participation in an Information ISAO a critical component of a medical device manufacturer’s comprehensive proactive approach to management of postmarket cybersecurity threats and vulnerabilities and a significant step towards assuring the ongoing safety and effectiveness of marketed medical devices.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Postmarket Management of Cybersecurity in Medical Devices.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>. Persons unable to download an electronic copy of “Postmarket Management of Cybersecurity in Medical Devices” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400044 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These

collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 803 (medical device reporting) have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 806 (reports of corrections and removals) have been approved under OMB control number 0910–0359; the collections of information in 21 CFR part 807, subpart E (premarket notification) have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 810 (medical device recall authority) have been approved under OMB control number 0910–0432; the collections of information in 21 CFR part 814 (premarket approval) have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 (quality system regulations) have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 822 (postmarket surveillance of medical devices) have been approved under OMB control number 0910–0449.

Dated: December 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31406 Filed 12–27–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2016–E–1179; FDA–2016–E–1181; FDA–2016–E–1182]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for IMLYGIC 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 human biological 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 27, 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 June 26, 2017. 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:* <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):* 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 Nos. FDA-2016-E-1179, FDA-2016-E-1181, and FDA-2016-E-1182 for “Determination of Regulatory Review Period for Purposes of Patent Extension; IMLYGIC.” Received comments will be

placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://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 <https://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 <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 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product IMLYGIC (talimogene laherparepvec). IMLYGIC is indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery. Subsequent to this approval, the USPTO received patent term restoration applications for IMLYGIC (U.S. Patent Nos. 7,063,835; 7,223,593; and 7,537,924) from BioVex Limited, and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of IMLYGIC 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 IMLYGIC is 3,809 days. Of this time, 3,352 days occurred during the testing

phase of the regulatory review period, while 457 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 (21 U.S.C. 355(i)) became effective:* May 25, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 25, 2005.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* July 28, 2014. FDA has verified the applicant's claim that the biologics license application (BLA) for IMLYGIC (BLA 125518) was initially submitted on July 28, 2014.

3. *The date the application was approved:* October 27, 2015. FDA has verified the applicant's claim that BLA 125518 was approved on October 27, 2015.

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 applications for patent extension, this applicant seeks 1,826 days, 1,764 days, or 1400 days, respectively, 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 <https://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.

Dated: December 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31322 Filed 12–27–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0067]

Pharmaceutical Science and Clinical Pharmacology Advisory Committee; Notice of Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled “Pharmaceutical Science and Clinical Pharmacology Advisory Committee; Notice of Meeting” that appeared in the **Federal Register** of November 29, 2016 (81 FR 85978). The document announced the forthcoming public advisory committee meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee. The document was published with an error in the **DATES** section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: ACPS-CP@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

In the **Federal Register** of Tuesday, November 29, 2016, in FR Doc. 2016–28723, the following correction is made:

On page 85978, in the third column, in the **DATES** section, the following sentence is to be inserted after the first sentence: “FDA is opening a docket for public comment on this meeting. The docket number is FDA–2010–N–0067. The docket will open for public comment on December 28, 2016. The docket will close on April 14, 2017.”

Dated: December 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31391 Filed 12–27–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Evaluation and Assessment of HRSA Teaching Health Centers

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than January 27, 2017.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Evaluation and Assessment of HRSA Teaching Health Centers.

OMB No. 0915–0376—Extension.

Abstract: The Teaching Health Center Graduate Medical Education (THCGME) program supports new and the expansion of existing primary care residency training programs in community-based settings. The primary goals of the THCGME program are to increase the production of primary care doctors and dentists who are well prepared to practice in community settings, particularly with underserved populations, and to improve the overall number and geographic distribution of primary care providers.