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]

BILLING CODE 4164–01–P

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]

BILLING CODE 4164–01–P

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.