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.

Need and Proposed Use of the Information: To ensure these goals are achieved, the George Washington University (GW) is conducting an evaluation of the training, administrative and organizational structures, clinical service, challenges, innovations, costs associated with training, and outcomes of Teaching Health Centers (THCs). GW has developed questionnaires for implementation with all THC matriculating residents, graduating residents, and graduated residents at one year post-graduation. The matriculation questionnaire aims to collect background information on THC residents to better understand the characteristics of individuals who apply and are accepted to THC programs. The graduation questionnaire collects information on career plans. The alumni questionnaire collects information on career outcomes (including practice in primary care and in underserved settings) following graduation as well as feedback on the quality of training.

Statute requires that THCGME program award recipients report annually on the types of primary care resident approved training programs provided, the number of approved training positions, the number who completed their residency at the end of the prior academic year and care for vulnerable populations living in underserved areas, and any other information as deemed appropriate by the Secretary. The described data collection activities will serve to meet this statutory requirement for the THCGME program award recipients in a uniform and consistent manner and will allow comparisons of this group to other trainees in non-THC programs. HRSA seeks renewal of these measures with no changes.

Likely Respondents: This data collection includes documents that are completed separately by THC Program Directors and residents. THC Program Directors who have not already completed the program data collection tool will respond to the part of the data collection tool related to the characteristics of the programs. Annual updates are made on an as-needed basis. THC matriculating residents, graduating residents and graduated residents at one year post-graduation will respond to the questionnaires related to characteristics of the residents.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Program Data Collection Tool	10	1	10	8	80
THC Alumni Survey	200	1	200	0.33	66
THC Matriculant Survey	200	1	200	0.25	50
THC Graduation Survey	200	1	200	0.25	50
Total	610		610		246

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–31353 Filed 12–27–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Small Health Care Provider Quality Improvement Program

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than February 27, 2017.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N–39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Small Health Care Provider Quality Improvement Program

OMB No. 0915–0387—Extension

Abstract: This program is authorized by Title III, Public Health Service Act, Section 330A(g) (42 U.S.C. 254c(g)), as amended by Section 201, P.L. 107–251, and Section 4, P.L. 110–355. This authority directs the Federal Office of Rural Health Policy (FORHP) to support grants that expand access to, coordinate, contain the cost of, and improve the quality of essential health care services, including preventive and emergency services, through the development of health care networks in rural and frontier areas and regions. Across these various programs, the authority allows HRSA to provide funds to rural and