approval of MAVYRET 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 MAVYRET is 1,725 days. Of this time, 1,492 days occurred during the testing phase of the regulatory review period, while 233 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* November 14, 2012. FDA has verified the applicant's claim that the date the investigational new drug applications became effective was on November 12, 2012.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 14, 2016. FDA has verified the applicant's claim that the new drug application (NDA) for MAVYRET (NDA 209394) was initially submitted on December 14, 2016.

3. *The date the application was approved:* August 3, 2017. FDA has verified the applicant's claim that NDA 209394 was approved on August 3, 2017.

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 0 days or 150 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: January 15, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00936 Filed 1–21–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: The Teaching Health Center Graduate Medical Education (THCGME) Program Reconciliation Tool, OMB No. 0915–0342—Extension

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 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 should be received no later than March 23, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

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

Information Collection Request Title: The Teaching Health Center Graduate Medical Education (THCGME) Program Reconciliation Tool OMB No. 0915–0342—Extension.

Abstract: The THCGME program, authorized by Section 340H of the Public Health Service Act, was established by Section 5508 of Public Law (Pub. L.) 111–148. The Bipartisan Budget Act of 2018 (Pub. L. 115–123) provided continued funding for the THCGME Program for fiscal years 2018 and 2019 and the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) extends funding for the THCGME program until May 22, 2020.

The THCGME program awards payment for both direct and indirect expenses to support training for primary care residents in community-based ambulatory patient care settings. Direct medical expense payments are designed to compensate eligible THC for those expenses directly associated with resident training, while indirect medical expense payments are intended to compensate for the additional costs of training residents in such programs.

Need and Proposed Use of the Information: THCGME program payments are prospective payments, and the statute provides for a reconciliation process, through which overpayments may be recouped and underpayments may be adjusted at the end of the fiscal year. This data collection instrument gathers information relating to the number of resident full-time equivalents in THC training programs in order to reconcile payments for both direct and indirect expenses.

Likely Respondents: THCGME program award recipients.

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
THCGME Reconciliation Tool	58	1	58	2	116
Total	58		58		116

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–00986 Filed 1–21–20; 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 Information Collection Request Title: Advanced Nursing Education Workforce (ANEW), OMB No. 0915–0375 Extension

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 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 should be received no later than March 23, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

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

Information Collection Request Title: Advanced Nursing Education Workforce (ANEW) Program-Specific Data Collection Forms OMB No. 0915–0375—Extension.

Abstract: HRSA provides advanced education nursing training grants to educational institutions to increase the numbers of advanced education nurses through the ANEW Program. The ANEW Program is authorized by Section 811 of the Public Health Service Act (42 U.S.C. 296j), as amended. This request is to extend the use of ANEW Program-Specific forms, specifically Tables #1 and #2. There are no proposed changes to these tables.

ANEW Table #1 collects information on the types of practice settings where graduates, who received ANEW support as students, are currently employed. The data on graduates' employment practice settings demonstrate the distribution of specialties, *i.e.,* nurse practitioners, clinical nurse specialists and nurse midwives, who are practicing in rural, underserved, public health nursing, and Health Professional Shortage Areas (HPSA) practice settings. ANEW Table #2 requests information on the projected number of primary care advanced practice registered nursing student enrollees/trainees who will receive traineeship support for each upcoming budget year over the entire project period. This data provides a baseline for comparison to data collected on the numbers of students/enrollees/trainees supported that are reported on the Annual Performance Reports.

Need and Proposed Use of the Information: ANEW Program-Specific Table #1 captures data on the number of graduates of the academic partner applicant who received HRSA support and are currently employed in rural areas, underserved areas, public health nursing, and HPSA practice settings. The graduate data collected measure the impact of the ANEW Program in meeting the legislative and program goals. ANEW Program-Specific Table #2 collects information on the projected number of students/enrollees to receive traineeship support each budget year of the project period and provides a baseline for student/enrollee support that is reported in the Annual Performance Reports. Collecting this data assists HRSA in carrying out the most impactful program and ensuring resources are used responsibly.

Likely Respondents: Likely respondents will be current ANEW awardees, who will submit the data tables as part of a Noncompeting Continuation progress report, and applicants for the ANEW program, including schools of nursing, nursing centers, academic health centers, state or local governments, and other public or private nonprofit entities determined appropriate by the Secretary that are accredited to carry out primary care nurse practitioner and nurse midwifery programs by a national nurse education accrediting agency recognized by the Secretary of the U.S. Department of Education. The school must be located in one of the 50 U.S. States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, the U.S. Virgin Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, or the Republic of Palau.

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