Staff. 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 § 10.20 (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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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 or biologic 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, VYZULTA (latanoprostene bunod). VYZULTA is indicated for reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Subsequent to this approval, the USPTO received patent term restoration applications for VYZULTA (U.S. Patent Nos. 7,273,946; 7,629,345; and 8,058,467) from Nicox S.A., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated May 13, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VYZULTA 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 VYZULTA is 3,879 days. Of this time, 3,043 days occurred during the testing phase of the regulatory review period, while 836 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:* March 23, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 23, 2007.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* July 21, 2015. FDA has verified the applicant's claim that the new drug application (NDA) for VYZULTA (NDA 207795) was initially submitted on July 21, 2015.

3. *The date the application was approved:* November 2, 2017. FDA has verified the applicant's claim that NDA 207795 was approved on November 2, 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 1,826 days or 1,507 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: February 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04178 Filed 2–28–23; 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; Maternal, Infant, and Early Childhood Home Visiting Program Home Visiting Program Budget Assistance Tool

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA 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. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than March 31, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments,'' or by using the search function.

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 Samantha Miller, the acting HRSA Information Collection Clearance Officer, at 301–594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Home Visiting Budget Assistance Tool (HV–BAT), OMB No. 0906–0025—Revision.

Abstract: HRSA is requesting an extension of approval and revision to the burden estimates for the HV–BAT. The tool collects information on standardized cost metrics from programs that deliver home visiting services. Entities receiving MIECHV formula funds that are states, jurisdictions, and nonprofit awardees are required to submit cost data using the HV–BAT to HRSA once every 3 years to be reviewed for accuracy and quality control and to collect data to estimate national program costs.

The MIECHV Program, authorized by section 511 of the Social Security Act, 42 U.S.C. 711, and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and for parents with young children up to kindergarten entry. States, tribal entities, and certain nonprofit organizations are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to local implementing agencies (LIAs) to provide services to eligible families in at-risk communities. HRSA is making the following changes to the HV–BAT:

- Updating the burden estimate for completing the HV–BAT based on recently gathered information. The burden estimate reflects both awardee and LIA staff hours to complete an HV–BAT. HRSA expects the majority of awardees will be submitting data from multiple LIAs, and some LIAs may submit multiple HV–BATs to account for each model implemented at their site.
- Translating the HV–BAT data collection instrument into Spanish to expand accessibility.

A 60-day notice was published in the **Federal Register** on November 8, 2022, 87 FR 67481–82. HRSA received five responses to the request for public comment. Two commentors are current MIECHV awardees, one is a home visiting model developer, one is a national membership organization representing MIECHV awardees, and one is a consultancy group directing a national initiative relating to home visiting. Commentors posed questions about the utility of HV–BAT data (*e.g.,* relevance of data collected from the prior year, lack of data context collected through the tool, how HRSA will account for variation in local labor markets) and of the specific data items collected (*e.g.,* necessity of collecting rural and frontier visit data, MIECHV funding percentages, and combined salary and fringe data). In addition, commentors provided recommendations for updating burden estimates and improving HRSA's technical assistance and feedback (*e.g.,* providing support for estimating in-kind costs and additional suggestions for review and feedback from HRSA).

HRSA views HV–BAT as an important tool for collecting standardized cost information across awardees, understanding the comprehensive costs of home visiting, and informing program planning and policy. During HV–BAT tool development, HRSA reviewed available cost measurement reports, tested the tool with awardees during the pilot and feasibility studies, and assessed the types of data that would be critical for understanding home visiting costs and funding allocation. Data categories within the tool were chosen to address these identified needs and fill in gaps in existing research. To ensure consistency in data collected across three cohorts of respondents, HRSA is not proposing to make updates to the data collection instrument itself at this time. However, in response to feedback on burden, the estimated average burden per response was increased from 24 to 40 hours, which includes burden on both LIAs and state-level awardees. In addition, awardees will have the option for HRSA to aggregate their LIA-level HV–BAT data, decreasing awardee burden. HRSA values the comments received regarding technical assistance, such as challenges with the tool and the utility of feedback received during the first round of submissions. HRSA is in the process of refining technical assistance materials and processes to better support awardees in response to these comments and to decrease awardee time spent on back-and-forth regarding HV–BAT revisions.

Need and Proposed Use of the Information: HRSA uses HV–BAT data to collect comprehensive home visiting cost data. Awardees submit aggregated data from their individual LIAs, which provides HRSA with information needed to produce state and national cost estimates and support procurement activities and subrecipient monitoring. Requiring data submission also allows HRSA to ensure the tool is being accurately and appropriately used. Because the use of a standardized tool of this kind is novel to the field of home visiting, HRSA requires that states submit data collected using HV–BAT to HRSA for the purposes of quality control reviews and accuracy checks. Submission will allow HRSA to estimate national-level costs for use in conducting research and analysis of home visiting costs, understanding cost variation, and assessing how comprehensive program cost data can inform other policy priorities, such as innovative financing strategies. HRSA is seeking to revise burden estimates to ensure accuracy and inform awardee planning for this activity. In addition, HRSA is translating the HV–BAT data collection instrument into Spanish in response to previous awardee feedback and to increase accessibility for LIA sites that primarily operate in Spanish.

Likely Respondents: One-third of MIECHV Program awardees (n=19, annually) that are states, jurisdictions, and nonprofit organizations receiving MIECHV funding to provide home visiting services within states.

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
Home Visiting Budget Assistance Tool	19	13	247	40	9,880
Total	19	13	247	40	9,880

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–04185 Filed 2–28–23; 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: Biographical Sketch Form for Use With Applications to the Maternal and Child Health Bureau Research Grants OMB No. 0906–Reinstatement

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 May 1, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to 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 Samantha Miller, 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: Forms for Use with Applications to the Maternal and Child Health Bureau Research Grants, OMB No. 0906-Reinstatement.

Abstract: HRSA is requesting reinstatement of the Biographical Sketch Form for use with applications to the Maternal and Child Health Bureau Research Grants (Biographical Sketch) for HRSA's SF424 Research and Related (R&R) application package. These grants are funded by a number of authorities such as 42 U.S.C. 701(a)(2) (title V, section 501(a)(2) of the Social Security Act) and by 42 U.S.C. 280i-1(f) (title III, section 399BB(f) of the Public Health Service Act. The purpose of these grants is to advance the health and well-being of Maternal and Child Health populations and children and adolescents with autism spectrum disorder by supporting innovative, applied, and translational intervention research studies on critical issues affecting these populations.

Need and Proposed Use of the Information: HRSA plans to use the Biographical Sketch as a required element of the SF424 R&R application package. The applicants use the Biographical Sketch form to summarize the qualifications of each key personnel on their proposed research team, including education/training, positions and honors, contributions to science, and related experience. The grant reviewers will use this information to assess the capabilities of the research team to carry out the planned research project. The Biographical Sketch form also collects demographic data (race, ethnicity, and gender) for the Principal Investigator and key program staff or, for applicants that are uncomfortable reporting this information, they can mark their demographic information as ''Not Reported/Unknown;'' this will have no impact on funding decisions. Collecting demographic information allows HRSA to determine to what extent individuals of different backgrounds are participating. This information, in addition to other information including career stage, geographic location of the institution, and educational level assists HRSA in ensuring that federal grant and cooperative agreement awards are reaching diverse populations.

HRSA is considering several changes for the Biographical Sketch:

- *Clarifying instructions:* Provides the applicant more information on what should and should not be included on the biographical sketch.
- *Removal of Section D:* Section D: Related Experience has been removed.
- *Removal of Section E:* Section E: Additional Information: Research Support and/or Scholastic Performance Awards has been removed.
- ''*Some Other Race*'' *Category:* At the request of our applicants, this category was added.

Likely Respondents: Respondents are applicants to HRSA's Maternal and Child Health Bureau research programs.

Burden Statement: Burden includes 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, disclosing and providing information. It also accounts for time to train personnel, respond to a collection of information, search data sources, complete and review the collection of information, and transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized Burden Hours: