this applicant seeks 789 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by May 30, 2014. 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 September 29, 2014. To meet its burden, the petition must 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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07060 Filed 3–28–14; 8:45 am]

BILLING CODE 4160–01–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

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (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 within 30 days of this notice.

ADDRESSES: Submit your comments, including the Information Collection Request 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: Reconciliation Tool for the Teaching Health Center Graduate Medical Education Program.

OMB No.: 0915–0342–Extension.

Abstract: The Teaching Health Center Graduate Medical Education (THCGME) program, Section 340H of the Public Health Service (PHS) Act, was established by Section 5508 of Public Law 111–148. The program supports training for primary care residents (including residents in family medicine, internal medicine, pediatrics, internal medicine pediatrics, obstetrics and gynecology, psychiatry, general dentistry, pediatric dentistry, and geriatrics) in community based ambulatory patient care settings.

The statute provides that eligible Teaching Health Centers receive payment for both direct and indirect expenses associated with training residents in community-based ambulatory patient care centers. Direct medical expenses payments are designed to compensate eligible teaching health centers for those expenses directly associated with resident training, while indirect medical expenses 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 will gather information relating to the numbers of residents in THCGME training programs in order to reconcile payments for both direct and indirect expenses.

Likely Respondents: The likely respondents to the THCGME Reconciliation Tool are existing 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	44	1	44	2	88
Total	44	1	44	2	88

Dated: March 11, 2014.

Jackie Painter,

Deputy Director, Division of Policy and Information Coordination.

[FR Doc. 2014–06999 Filed 3–28–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request: Generic Clearance To Support the Safe to Sleep Campaign at the Eunice Kennedy Shriver National Institute for Child Health and Human Development (NICHD)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development, the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on December 30, 2013, pages 79472–79473 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Child Health and Human Development, National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Dr. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Drive, Room 2A18, Bethesda, Maryland 20892, or call a non-toll free number (301) 496–1877 or Email your request, including your address to *glavins@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Generic Clearance to Support the Safe to Sleep Campaign at the *Eunice Kennedy Shriver* National Institute for Child Health and Human Development (NICHD), 0925—NEW, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a request for a new generic clearance that would be used for submissions specific to the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Safe to Sleep (STS) public education campaign. Submissions for the STS campaign will be used to assess the understanding and reach of STS campaign materials and messages, and to monitor and improve campaign activities such as training workshops and overall implementation. The purpose of this information collection is to monitor and modify campaign activities, to plan future campaign activities, to develop messages and materials, and to develop distribution and outreach strategies that are effective at communicating their message to bring about the intended response, awareness, and/or behavioral change for the target audiences. This generic clearance will enable the NICHD to: (1) More efficiently assess the implementation of campaign activities; (2) better understand the target audiences' knowledge, attitudes, and beliefs toward STS messages and materials; (3) better understand how the campaign activities have influenced the target audiences' behaviors and practices; and (4) monitor and improve activities such as trainings, and material/message development. Having a way to gather feedback on the STS campaign activities is critical to assessing the reach and effect of campaign efforts. Data collected for the campaign can inform where future STS campaign resources can produce the most meaningful results.

Data collected for the STS campaign generic clearance will be used by a number of audiences, including STS campaign staff, NICHD leadership, STS campaign collaborators, Federal Sudden and Unexpected Infant Deaths (SUID)/Sudden Infant Death Syndrome (SIDS) Workgroup members, SUID/SIDS stakeholders, clinical and maternal/child health professionals, parents and caretakers, and the general public. These audiences may use the information collections to: (1) Develop new campaign messages, materials, and/or training curricula; (2) monitor and improve campaign activities; (3) make decisions about campaign activities; (4) inform current campaign activities; and (5) inform and/or change practices and behaviors of program participants.

Examples of the types of information collections that could be included under this generic clearance include: *Focus groups and in-depth interviews* with parents/caregivers and/or health professionals to get feedback on distribution and outreach activities, and/or campaign messages; and *Surveys* with parents/caregivers and/or health professionals to: (1) Assess the usefulness of the new STS campaign materials, including print and on-line materials and a video, (2) track outreach experiences of program participants, (3) assess training participants' changes in knowledge related to safe infant sleep behavior and implementation of outreach methods taught, and (4) assess program participants' resource needs.

The sub-studies for this generic will be small scale, designed to obtain results frequently and quickly to guide campaign development and implementation, inform campaign direction, and be used internally for campaign management purposes. NICHD's current scope and capacity for STS generic sub-studies is non-existent and this request would fill this gap.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 3,000.

Estimated Annualized Burden Hours