phase of the regulatory review period, while 358 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:* July 29, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 29, 2010.

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):* February 27, 2018. FDA has verified the applicant's claim that the biologics license application (BLA) for ESPEROCT (BLA 125671) was initially submitted on February 27, 2018.

3. *The date the application was approved:* February 19, 2019. FDA has verified the applicant's claim that BLA 125671 was approved on February 19, 2019.

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 application for patent extension, this applicant seeks 1,170 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: March 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05658 Filed 3–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Council on Graduate Medical Education

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

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates for consideration for appointment as members of the Council on Graduate Medical Education (COGME or Council). COGME provides advice and recommendations on policy, program development, and other matters of significance concerning the physician training and the physician workforce. Issues addressed by COGME include the supply and distribution of the physician workforce in the United States, including any projected shortages or excesses of physicians in medical and surgical specialties and subspecialities; international medical graduates; the nature and financing of undergraduate and graduate medical education; appropriation levels for certain programs under title VII of the PHS Act; and deficiencies in databases of the supply and distribution of the physician workforce and postgraduate programs for training physicians.

DATES: HRSA will accept nominations on a continuous basis.

ADDRESSES: Nomination packages may be mailed to Advisory Council Operations, Bureau of Health Workforce, HRSA, Room 15N–35, 5600 Fishers Lane, Rockville, Maryland 20857 or submitted electronically by email to: *BHWAdvisoryCouncilFRN@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Curi Kim, M.D., MPH, at 240–472–2313 or email at *ckim@hrsa.gov.* A copy of the current COGME charter, membership, and reports can be obtained by accessing the COGME website at *https://www.hrsa.gov/advisory-committees/graduate-medical-edu.*

SUPPLEMENTARY INFORMATION: Authorized in 1986, COGME submits advice and recommendations to the Secretary of HHS; the Senate Committee on Health, Education, Labor and Pensions; and the House of Representatives Committee on Energy and Commerce. Additionally, COGME encourages entities providing graduate medical education to voluntarily achieve the recommendations of the Council. Meetings take place at least twice per year.

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees on COGME to include individuals who represent of practicing primary care physicians, national and specialty physician organizations, international medical graduates, medical student and house staff associations, schools of allopathic and osteopathic medicine, public and private teaching hospitals, and health insurers, business, and labor. The Secretary of HHS appoints COGME members to fulfill the duties of the Council. Interested applicants may self-nominate or be nominated by another individual or organization.

Individuals selected for appointment to COGME will be invited to serve for 4 years. Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending COGME meetings and/or conducting other business on behalf of COGME, as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service and PHS Act section 762(g).

A nomination package should include the following information for each applicant: (1) if nominated by another individual or organization, a letter of recommendation from the nominator stating the basis for the nomination (*i.e.,* what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of COGME) and the nominee's field(s) of expertise as well as the nominator's name, affiliation, and contact information (address, daytime telephone number, and email address); (2) a letter of interest from the applicant stating the reasons the applicant would like to serve on COGME; and (3) a biographical sketch of the applicant, including the applicant's curriculum vitae and contact information (address, daytime telephone number, and email address). Nomination packages may be submitted directly by the applicant or by the person/organization nominating the candidate.

HHS endeavors to ensure that the membership of COGME is balanced fairly in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, and ethnic and minority groups, as well as individuals with

disabilities, are considered for membership. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and or cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is required for HRSA ethics officials to determine whether there is a potential conflict of interest between the Special Government Employee's public duties as a member of COGME and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any required remedial action needed to address the potential conflict.

Authority: PHS Act Section 762 (42 U.S.C. 294o), as amended. COGME is governed by provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. 10), which sets forth standards for the formation and use of advisory committees and applies to the extent that the provisions of the Federal Advisory Committee Act do not conflict with the requirements of PHS Act section 762.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–05782 Filed 3–20–23; 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: Evaluation of the Maternal and Child Health Bureau's Autism CARES Act Initiative, OMB No. 0915–0335–Revision

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 must be received no later than May 22, 2023.

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

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

Information Collection Request Title: Evaluation of the Maternal and Child Health Bureau's Autism CARES Act Initiative, OMB No. 0915–0335–Revision.

Abstract: HRSA's Maternal and Child Health Bureau (MCHB) provides funds to support several programs related to autism, as authorized by 42 U.S.C. 280i–1 (title III, section 399BB of the Public Health Service Act), as amended by the Autism Collaboration, Accountability, Research, Education, and Support (CARES) Act of 2019 (Pub. L. 116–60). The Autism CARES Act of 2019 emphasizes improving health outcomes and the well-being of individuals with Autism Spectrum Disorder and Developmental Disabilities across the lifespan.

MCHB's programs related to autism fall within three distinct but complementary areas—research, state systems, and training. The awards advance research on early screening and interventions for autism and developmental disabilities; improve the capacity of state public health agencies to build and maintain coordinated systems of services for individuals with autism and developmental disabilities; and train the health care workforce to screen, refer, and provide services for children and youth with autism and developmental disabilities. MCHB currently funds 12 programs and 95 awardees. HRSA seeks to implement annual comprehensive evaluations of MCHB's Autism CARES Initiative investments.

This ICR is a revision to an existing package; this study is the fifth evaluation of HRSA's autism activities and employs similar data collection methodologies as the prior studies. Grantee interviews remain the primary form of data collection. Minor proposed revisions to the data collection process include modifications to the interview questions and grantee survey based on the current legislation and HRSA's Notices of Funding Opportunity for programs authorized under the Autism CARES Act. In addition, the previous data collection compiled survey responses from all grantees, whereas this revised data collection will only seek survey responses from the Research and State Systems grantees. The previous data collection also included a quantitative data collection form for the Research grantees that the current data collection will not collect. These changes result in fewer burden hours estimated across all primary data collection activities.

Need and Proposed Use of the Information: The purpose of this data collection is to implement a comprehensive evaluation that describes the activities, accomplishments, outcomes, barriers, and challenges of the grant programs in implementing the provisions of the Autism CARES Act. The data will be used to (1) conduct performance monitoring of the programs; (2) provide credible and rigorous evidence of program effectiveness; (3) meet program needs for accountability, decision-making, and quality assurance; and (4) strengthen the evidence base for best practices.

Likely Respondents: The survey respondents will include Principal Investigators/Project Directors from the research programs and networks (Autism Intervention Research Network on Physical Health, Autism Intervention Research Network on Behavioral Health, MCHB Secondary Data Analysis Research Program, Autism Field-Initiated Innovative Research Studies Program, Autism Single Investigator Innovation Program, the Developmental-Behavioral Pediatrics Research Network, and the Healthy Weight Research Network for Children with Autism and Other Developmental Disabilities); and state systems programs (State Innovations) and coordinating center (State Public Health Coordinating Center for Autism). The respondents for the interviews will include Principal Investigators/Project Directors from the research and state systems programs above, and the training programs (Leadership Education in Neurodevelopmental and Related Disabilities program, the Developmental Behavioral Pediatrics program, and the National Interdisciplinary Training Resource Center).