reconsideration. The information collection requirements 42 CFR 478.18, 478.34, 478.36, and 478.42, contain procedures for QIOs to use in reconsideration of initial determinations. The information requirements contained in these regulations are on QIOs to provide information to parties requesting the reconsideration. These parties will use the information as guidelines for appeal rights in instances where issues are actively being disputed. *Form Number:* CMS–R–72 (OMB control number: 0938–0443); *Frequency:* Reporting—On occasion; *Affected Public:* Individuals or Households and Business or other for-profit institutions; *Number of Respondents:* 20,129; *Total Annual Responses:* 60,489; *Total Annual Hours:* 22,014. (For policy questions regarding this collection contact Kimberly Harris at 617–565–1285).

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Generic Beneficiary and Family Centered-Care Quality Improvement Organization (BFCC–QIO) Data Collection Research; *Use:* The purpose of this submission is to request approval for generic clearance that covers a program of data collection activities to obtain feedback from a broad audience that may include, but will not be limited to Medicare beneficiaries, their family, health care providers and other key stakeholders who have used or may use and have been impacted by the BFCC–QIO services and its offerings. This data collection effort is part of a strategic plan to obtain direct feedback from Medicare beneficiaries, their family, health care providers and other key stakeholders on QIO process improvement efforts and their satisfaction with the services provided by these BFCC–QIOs. Feedback obtained will be used to improve the BFCC QIO program. With the approval of this clearance, the Division of Beneficiary Reviews and Care Management (DBRCM) will be able to maintain a proactive process for rapid data collection to inform the work of the BFCC–QIO program around new and existing initiatives, as well as providing rapid feedback on service delivery and satisfaction for continuous improvement of the BFCC–QIO program.

The BFCC–QIO program is statutorily mandated to improve the quality of healthcare services Medicare beneficiaries receive. BFCC–QIOs provide the foundational level of quality in the health care system by investigating quality of care complaints made by Medicare beneficiaries and their families; by providing an avenue for appeals if they feel they are being released from a facility too soon; by requesting for immediate advocacy services when they have concerns about their care that need a quick resolution; and by providing care management services to help people with Medicare navigate the healthcare system and coordinate their care. The BFCC–QIOs provide these essential services for beneficiaries and families of the national Medicare program.

This generic clearance will cover a program of qualitative (in-depth interviews and focus group interviews), and quantitative methods (surveys) to obtain feedback from a wide range of audience that may include, but will not be limited to Medicare beneficiaries, their family, healthcare providers and any other key audiences that would support CMS in informing and improving QIO services, and any new and existing initiatives. *Form Number:* CMS–10783 (OMB control number: 0938–NEW); *Frequency:* Occasionally; *Affected Public:* Individuals and Households; *Number of Respondents:* 16,800; *Total Annual Responses:* 191,200; *Total Annual Hours:* 59,400. For policy questions regarding this collection, contact Yewande Oladeinde at 410–786–2157.)

Dated: September 22, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–20978 Filed 9–27–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0689]

Public Workshop: Analgesic Clinical Trial Designs, Extrapolation, and Endpoints in Patients From Birth to Less Than Two Years of Age

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Analgesic Clinical Trial Designs, Extrapolation, and Endpoints in Patients from Birth to Less Than Two Years of Age.'' The purpose of the public workshop is to discuss the state of science, data gaps, and challenges in drug development for drugs intended to treat acute pain in patients less than 2 years of age.

DATES: The public workshop will be held virtually on October 13 and 14, 2021, from 10 a.m. to 2 p.m. Eastern Standard Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held in virtual format only and will not be held at a specific location. Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this public meeting via an online teleconferencing platform. The public workshop will be held at *https://go.umd.edu/analgesic-clinical-trial.*

FOR FURTHER INFORMATION CONTACT: Heather Buck at *Heather.Buck@fda.hhs.gov,* 301–796–1413 or Kerri-Ann Jennings at *Kerri-Ann.Jennings@fda.hhs.gov,* 301–796–2919, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Rm. 6467, Silver Spring, MD 20903–0002.

SUPPLEMENTARY INFORMATION:

I. Background

In 2009, FDA convened a scientific workshop with experts in pediatric pain, pediatric clinical trial design, pediatric ethics, and pediatric drug development [1]. Based on the available data at the time, the expert panel recommended extrapolation of efficacy in patients 2 years and older, relying on matching effective drug exposures in adults. The current approach to study drugs with well-established mechanisms of action, such as opioids, non-steroidal anti-inflammatory drugs (NSAIDS), acetaminophen, and local anesthetics, relies on matching safe and effective drug exposures in adults to support the efficacy of drugs used to treat acute pain in pediatric patients at least 2 years of age. Controlled efficacy trials are only required in patients from birth to less than 2 years of age. When controlled efficacy trials are needed, FDA has recommended an ''add-on'' design using opioid-sparing calculation rather than the change in pain intensity used in efficacy trials of analgesics in adults.

Despite these advances in clinical trial design, there continues to be unmet needs in the availability of products to treat acute pain, especially in patients less than 2 years of age. There is currently only one analgesic labeled for use in patients less than 2 years of age: Ibuprofen is approved for the treatment

[1] Berde, CB, et.al., Pediatrics 2012 Feb;129(2):354–64. *https://www.fda.gov/advisory-committees/advisory-committee-calendar/april-12-2016-pediatric-advisory-committee-meeting-announcement-04122016-04122016.*

of pain in children 6 months of age and older. Furthermore, controlled trials in patients less than 2 years of age have been difficult to complete and the data obtained from completed trials have often been difficult to interpret.

The purpose of the public workshop is to discuss the current state of therapies to treat acute pain in children, identify data gaps, and consider methods to improve the current drug development paradigm for acute pain in patients less than 2 years of age (*e.g.,* use of pediatric extrapolation, and novel clinical trial designs). The workshop is intended to focus on drugs with well-established mechanisms of action (NSAIDs, acetaminophen, local anesthetics, opioids), rather than drugs with novel mechanisms of action.

II. Topics for Discussion at the Public Workshop

The main objective of the ''Analgesic Clinical Trial Designs, Extrapolation, and Endpoints in Patients from Birth to Less Than Two Years of Age'' workshop is to discuss the current state of therapies to treat acute pain in children, identify data gaps, and discuss feasible trial designs and methods (*e.g.,* use of pediatric extrapolation) to improve the current drug development paradigm for acute pain in patients less than 2 years of age. The workshop will include regulators, industry, academia, and patient organizations to optimize the discussion of the selected topics.

III. Participating in the Public Workshop

Registration: Please visit the following website to register for this public workshop: *https://go.umd.edu/analgesic-clinical-trial.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast at the following site: *https://collaboration.fda.gov/rz3mubd491lo/.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* For an overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: September 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21000 Filed 9–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of the National Coordinator for Health Information Technology; Delegation of Authority

Notice is hereby given that I have delegated to the National Coordinator for Health Information Technology (National Coordinator), Office of the National Coordinator for Health Information Technology (ONC), or his or her successor, the authority vested in the Secretary of Health and Human Services: (a) To administer the provisions of subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 *et seq.*), as amended, as specified under section 3001 (with the exception of section 3001(a)) and section 3009A; (b) to administer the provisions of subtitle C of title XXX of the Public Health Service Act (42 U.S.C. 300jj–52), as amended, as specified under section 3022 (with the exception of section 3022(b) and (d)(4)); (c) to administer the provisions of title II, subtitle E, section 2401(b)(5) of the American Rescue Plan Act of 2021 (Pub. L. 117–2), for the purpose of carrying out COVID–19 activities related to enhancing information technology, data modernization, and reporting, including improvements necessary to support sharing of data related to public health capabilities; and (d) to administer the provisions of title II, subtitle F, section 2501 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), for the purpose of carrying out COVID–19 activities related to establishing, expanding, and sustaining a public health workforce by making awards of funds.

Limitations

This delegation of authority may be re-delegated.

The Secretary retains the authority to submit reports to Congress, promulgate regulations, and to establish advisory committees and councils and appoint their members, as applicable.

Previous delegations made to officials within the Department of Health and Human Services for authority under title II, subtitle E, section 2401(b)(5), and title II, subtitle F, section 2501 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) continue in effect.

Exercise of this authority shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the Secretary.

I hereby affirm and ratify any actions taken by the National Coordinator, or his or her subordinates, which involved the exercise of the authority delegated herein prior to the effective date of this delegation.

Effective Date

This delegation is valid upon date of signature.

Authority

5 U.S.C. 301; section 6 of the Reorganization Plan No. 1 of 1953; and section 2 of the Reorganization Plan No. 3 of 1966.

Dated: September 23, 2021.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2021–21140 Filed 9–24–21; 4:15 pm]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Initial Review Group.

Date: October 21–22, 2021.

Time: 9:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Nursing Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Cheryl Nordstrom, Ph.D., Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Suite 703H Bethesda, MD 20892, (301) 827–1499, *cheryl.nordstrom@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)