are required and fewer rebuttals are expected.

Dated: June 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12109 Filed 6–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0001]

Leveraging Randomized Clinical Trials To Generate Real-World Evidence for Regulatory Purposes; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Leveraging Randomized Clinical Trials to Generate Real-World Evidence for Regulatory Purposes.'' Convened by Duke University's Robert J. Margolis, MD, Center for Health Policy (Duke Margolis) and supported by a cooperative agreement with FDA, the purpose of the public workshop is to bring the stakeholder community together to explore key considerations for using randomized designs, such as large simple trials or those that incorporate pragmatic elements to generate real-world evidence (RWE).

DATES: The public workshop will be held on July 11, 2019, from 8:30 a.m. to 5 p.m., Eastern Time and July 12, 2019, from 9 a.m. to 1 p.m., Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at The Westin City Center, 1400 M St. NW, Washington, DC 20005. For additional travel and hotel information, please refer to the following website: *https://healthpolicy.duke.edu/events/leveraging-randomized-clinical-trials-and-real-world-data-generate-real-world-evidence*. There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Workshop*).

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993, 301–796–2500, *Dianne.Paraoan@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3022 of the 21st Century Cures Act (Cures Act) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 505F, *Utilizing real world evidence* (21 U.S.C. 355g). This section requires the establishment of a program to evaluate the potential use of RWE to help support the approval of a new indication for a drug approved under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) and to help to support or satisfy postapproval study requirements. In December 2018, FDA published the Framework for the RWE program (*https://www.fda.gov/media/120060/download*). To inform FDA's RWE Framework, on September 13, 2017, through its cooperative agreement with Duke Margolis, FDA convened a public meeting that explored the use of RWE for regulatory decisions.

The RWE Framework includes information describing sources of RWE, gaps in data collection activities, standards and methodologies for collecting and analyzing RWE, and priority areas, remaining challenges, and potential pilot opportunities to address the overarching Cures Act requirements. The RWE Framework also discusses the integration of clinical trials into clinical care settings and FDA's intent to issue guidance on this subject. The public workshop announced in this notice is a part of FDA's ongoing efforts to implement the RWE Framework by exploring the utility of RWE for regulatory decision making. This workshop will focus on how randomized clinical trial designs can use real-world data (RWD) to generate RWE, particularly in clinical care settings.

II. Topics for Discussion at the Public Workshop

This workshop will explore key considerations for using randomized clinical trial designs and RWD to generate RWE, particularly in clinical care settings. Considerations for discussion include: (1) Selection of interventions appropriate in clinical care settings, (2) study design elements and study populations, (3) capturing outcomes in clinical care settings, and (4) addressing potential challenges around blinding, randomization, and bias. The workshop will also explore regulatory considerations for randomized clinical trials using RWD, such as safety and product monitoring and maintaining data integrity.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://healthpolicy.duke.edu/events/leveraging-randomized-clinical-trials-and-real-world-data-generate-real-world-evidence*. There will be no onsite registration. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by July 10, 2019, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been registered. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy (phone: 202–791–9561, email: *sarah.supsiri@duke.edu*) no later than July 5, 2019.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast, and archived video footage will be available at the Duke-Margolis website (*https://healthpolicy.duke.edu/events/leveraging-randomized-clinical-trials-and-real-world-data-generate-real-world-evidence*) following the workshop. Persons interested in viewing the live webcast are encouraged to register in advance (see *Registration*). Organizations are requested to register all participants, but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements in advance of the event. Prior to joining the streaming webcast of the public workshop, it is recommended that you review these technical system requirements. 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.

Meeting Materials: All event materials will be provided to registered attendees via email prior to the workshop and publicly available at the Duke-Margolis website (*https://healthpolicy.duke.edu/events/leveraging-randomized-clinical-trials-and-real-world-data-generate-real-world-evidence*).

Transcripts: Transcripts of the public workshop will not be available.

Dated: June 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–12113 Filed 6–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request: 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 10, 2019.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Title of the Collection: State-Level Paid Family Leave Policy Project.

Type of Collection: New.

0990–NEW—Office of the Secretary/ Office on Women's Health (OWH)

Abstract: The Department of Health and Human Services (DHHS) Office on Women's Health (OWH) ''provides national leadership and coordination to improve the health of women and girls through policy, education, and innovative programs.'' Through the State-Level Paid Family Leave Policy Project, OWH will explore the relationship between women's health and state-level paid family leave (PFL) programs, which provide partial wage replacement to eligible employees to bond with a new child. The project aims to increase awareness of women's health effects in relation to state-level PFL programs among key stakeholders, including advocates, state and federal policymakers, and state program administrators. This information will be used to inform the national conversation about these programs.

The State-Level Paid Family Leave Policy Project involves the collection of information on new mothers' health, health behaviors, and ability to fulfill their roles in the workplace, family and community. Data will be collected through 16 one-time focus groups in the four states with fully functioning state-level PFL programs (California, New Jersey, Rhode Island, and New York) with both women who used and women who did not use the program. A questionnaire will be administered prior to the focus groups to collect information on participants' demographic characteristics and other external factors that may affect health. Data collection and analysis will take approximately one year.

Interested individuals will be screened for eligibility. Participants must be mothers with a child under the age of one and be eligible for their state's respective PFL program. To participate as a state-level PFL user, mothers must have used the entire state-level PFL benefit. To participate as a state-level PFL non-user, mothers must have a baby older than the ''state-level PFL threshold'' and have not taken any state-level PFL. We define the threshold as the time after which mothers are typically out of the temporary disability insurance (TDI) and state-level PFL window (approximately 12 weeks).

ANNUALIZED BURDEN HOUR TABLE

Forms	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (within hours)	Total burden hours
Focus group screener	Interested Individuals	384	1	15/60	96
Demographic questionnaire	Focus group participants	96	1	15/60	24
Focus group protocol	Focus group participants	96	1	1.25	120
Total					240

Terry Clark,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2019–12098 Filed 6–7–19; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center For Complementary & Integrative Health; 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 Center for Complementary and Integrative Health Special Emphasis Panel; NCCIH Training, Fellowship, and Career Development Review Panel (CT).