include inaccurate participant reports of drug use, high rates of missing data, the confounding effects of concomitant drug treatments, and the need to demonstrate the durability of the device's treatment effect, which can necessitate prolonged observation.

A notice of availability of the draft guidance appeared in the **Federal Register** of July 28, 2023 (88 FR 48888). FDA considered comments received and has made some minor edits for clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Clinical Considerations for Studies of Devices Intended To Treat Opioid Use Disorder. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all CDRH guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Clinical Considerations for Studies of Devices Intended To Treat Opioid Use Disorder'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00019017 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
860, subpart D	De Novo classification process	0910–0844

Dated: July 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15130 Filed 7–10–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Clinical Trials and Comparative Effectiveness Research in Neurology, July 09, 2024, 09:00 a.m. to July 10, 2024, 02:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 which was published in the **Federal Register** on June 13, 2024, FR Doc. 2024–13021, 89 FR 50347.

This notice is being amended to change the dates of this two-day meeting from July 9, 2024, and July 10, 2024, to July 29, 2024, and July 30, 2024. The meeting time remains the same. The meeting is closed to the public.

Dated: July 5, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–15187 Filed 7–10–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Early Phase Clinical Trials in Neurology, July 10, 2024, 02:00 p.m. to July 10, 2024, 05:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, which was published in the **Federal Register** on June 13, 2024, FR Doc. 2024–13021, 89 FR 50347.

This notice is being amended to change the date of this one-day meeting from July 10, 2024, to July 30, 2024. The meeting time remains the same. The meeting is closed to the public.

Dated: July 5, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–15188 Filed 7–10–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Vaccine (and Other

Biologic) Manufacturing Services for Infectious Diseases.

Date: July 26–August 16, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20852 (Video Assisted Meeting).

Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20852, (240) 669–5931, *jakesse@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 5, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–15220 Filed 7–10–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Meeting of the Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention National Advisory Council

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given for the meeting on August 27, 2024, of the Center for Substance Abuse Prevention National Advisory Council (CSAP NAC). The meeting is open to the public and can also be accessed virtually. Agenda with call-in information will be posted on the SAMHSA website prior to the meeting at: *https://www.samhsa.gov/about-us/advisory-councils/meetings.* The meeting will include, but not be limited to, remarks from the Assistant Secretary for Mental Health and Substance Use; approval of the meeting minutes of February 27, 2024; an update from the CSAP NAC Substance Use Prevention Workforce Subcommittee; overview and discussion on CSAP's primary prevention portfolio; Council discussion and public comments.

DATES: August 27, 2024, 9:00 a.m. to approximately 4:00 p.m. EDT, Open.

ADDRESSES: 200 Independence Ave. SW, Washington, DC 20201 (Room 425A).

FOR FURTHER INFORMATION CONTACT: CAPT Jennifer Fan, PharmD, JD, Designated Federal Official; Substance Abuse and Mental Health Service Administration, CSAP National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail); telephone: (240) 276–0422; email: *Jennifer.fan@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: The CSAP NAC was established to advise the Secretary, Department of Health and Human Services (HHS), and the Assistant Secretary for Mental Health and Substance Use, SAMHSA; and the Director, CSAP, concerning matters relating to the activities carried out by and through the Center and the policies respecting such activities.

Interested persons may present data, information, or views orally or in writing, on issues pending before the Council. Written submissions must be forwarded to the contact person no later than 7 days before the meeting. Oral presentations from the public will be scheduled for the public comment section at the end of the council discussion. Individuals interested in making oral presentations must notify the contact person by 1:00 p.m. (EDT), August 20, 2024. Up to three minutes will be allotted for each presentation, and as time permits, as these are presented in the order received. Public comments received will become part of the meeting records.

To obtain the call-in number, access code, and/or web access link; submit written or brief oral comments; or request special accommodations for persons with disabilities, please register on-line at: *https://snacregister.samhsa.gov,* or communicate with the contact person. Meeting information and a roster of Council members may be obtained either by accessing the CSAP Council's website at *https://www.samhsa.gov/about-us/advisory-councils,* or by contacting Jennifer Fan.

Authority: Public Law 92–463.

Dated: July 5, 2024.

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2024–15245 Filed 7–10–24; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2014–0022]

Technical Mapping Advisory Council; Meeting

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The Federal Emergency Management Agency (FEMA) Technical Mapping Advisory Council (TMAC) will hold an in-person public meeting with a virtual option on Thursday, August 29, 2024, and Friday, August 30, 2024. The meeting will be open to the public in-person and via a Microsoft Teams Video Communications link.

DATES: The TMAC will meet on Thursday, August 29, 2024 and Friday, August 30, 2024, from 8:00 a.m. to 5:00 p.m. Eastern Time (ET). Please note that the meeting will close early if the TMAC has completed its business.

ADDRESSES: The meeting will be held in person at 400 C Street SW, Washington, DC 20472 and virtually using the following Microsoft Teams Video Communications link (Thursday Link: *https://tinyurl.com/yskff3sz:* Friday Link: *https://tinyurl.com/yskff3sz*). Members of the public who wish to attend the in-person or virtual meeting must register in advance by sending an email to *FEMA-TMAC@fema.dhs.gov* (Attn: Brian Koper) by 5:00 p.m. ET on Monday, August 26, 2024.

To facilitate public participation, members of the public are invited to provide written comments on the issues to be considered by the TMAC, as listed in the **SUPPLEMENTARY INFORMATION** caption below. Associated meeting materials will be available upon request after Friday, August 23, 2024. To receive a copy of any relevant materials, please send the request to: *FEMA-TMAC@fema.dhs.gov* (Attn: Brian Koper). Written comments to be considered by the committee at the time of the meeting must be submitted and received by Monday, August 26, 2024, 5:00 p.m. ET identified by Docket ID FEMA–2014–0022, and submitted by the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email:* Address the email to *FEMA-TMAC@fema.dhs.gov.* Include the docket number in the subject line of the