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A notice of availability of the draft guidance appeared in the **Federal Register** of July 28, 2023 (88 FR 48888).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