

domestic pharmaceutical manufacturers.

Registration is free and based on space availability, with priority for in-person participation given to registrants that, in FDA's view, represent higher priority areas for Domestic Manufacturing. Persons interested in attending this public meeting must register by September 2, 2025, 11:59 p.m. Eastern Time. Register to attend the public meeting in-person or virtually at this link: <https://www.fda.gov/drugs-news-events-human-drugs/fda-public-meeting-onshoring-manufacturing-drugs-and-biological-products-09302025>. Early registration is recommended because seating is limited. For this meeting, FDA is limiting the number of in-person participants per company/entity to facilitate a broad representation of the drug manufacturing industry. FDA will confirm registration for in-person participants based on the information requested above. Registrants that are not confirmed for in person participation may join the meeting virtually.

If you need special accommodations due to a disability, please contact Maya Thompson, Office of External Affairs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5335, Silver Spring, MD 20993-0001, 301-837-7398, *PublicEngagement@fda.hhs.gov* no later than September 23, 2025.

Virtual Participation in the Public Meeting: The public will also have the option to participate through an online teleconferencing and/or video conferencing platform. This public meeting will also be webcast. Virtual attendees will receive a confirmation email containing the website link after their registration has been submitted.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at FDA website at <https://www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-onshoring-manufacturing-drugs-and-biological-products-09302025>.

Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Dated: August 5, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/>.

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/or 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 grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Neurological Disorders and Stroke Council

Date: September 3-4, 2025.

Open: September 03, 2025, 10:00 a.m. to 3:00 p.m.

Agenda: Report by the Director, NINDS; Report by the Director, Division of Extramural Activities; and Administrative and Program Developments.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, Virtual Meeting.

Closed: September 03, 2025, 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, Virtual Meeting.

Closed: September 04, 2025, 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, Virtual Meeting.

Contact Person: Andrea Meredith, Ph.D., Director of Extramural Activities, National Institute of Neurological Disorders and Stroke, NIH, 6001 Executive Blvd., 5th Floor, MSC 9531, Bethesda, MD 20892, (301) 496-9248, andrea.meredith@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: www.ninds.nih.gov, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: August 5, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Council of Councils.

The meeting will be held as a hybrid meeting held in-person and virtually and is open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations, to view the meeting should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting website <http://videocast.nih.gov/>.

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,