readiness for products with accelerated clinical development.

Based on lessons learned from the Agency's experience with submissions involving accelerated clinical development, especially those through the pilot, the discussions during the September 10, 2025, workshop, and other public input, this Strategy Document outlines the specific activities FDA has undertaken or intends to undertake to facilitate CMC development for products with accelerated clinical development timelines. These include: continuing to provide opportunities for enhanced communication and the application of risk-based, scientific, and regulatory strategies to sponsors with a Breakthrough Therapy, Fast-Track, or Regenerative Medicine Advanced Therapy Designation; and providing regulatory flexibilities as described in CDER's existing MAPP 5015.13 and CBER's newly published flexibilities for cell and gene therapies (see the announcement at link: *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/flexible-requirements-cell-and-gene-therapies-advance-innovation* and the guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/chemistry-manufacturing-and-controls-flexibilities-developing-human-cellular-and-gene-therapy*).

The Strategy Document will be made available on the following FDA web page:

- Chemistry, Manufacturing, and Controls Development and Readiness Pilot (CDRP) Program, available at: *https://www.fda.gov/drugs/pharmaceutical-quality-resources/chemistry-manufacturing-and-controls-development-and-readiness-pilot-cdrp-program*.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14898 Filed 7–22–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0008]

Advisory Committee; Peripheral and Central Nervous System Drugs Advisory Committee; Termination and Reestablishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; termination and reestablishment of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination and reestablishment of the Peripheral and Central Nervous System Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Peripheral and Central Nervous System Drugs Advisory Committee was terminated on June 4, 2026, because its charter was not renewed on or before that expiration date. The Commissioner has determined that it is in the public interest to reestablish the Peripheral and Central Nervous System Drugs Advisory Committee for 2 years from the date it is reestablished.

DATES: Authority for the Peripheral and Central Nervous System Drugs Advisory Committee will reestablish on July 30, 2026.

FOR FURTHER INFORMATION CONTACT: Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3215, Silver Spring, MD 20993–0002, (301) 796–8220, *ACOMSSubmissions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 21 CFR 14.55(b); 21 CFR 14.40(b) and 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the termination and reestablishment of the Peripheral and Central Nervous System Drugs Advisory Committee (the Committee). The Committee was terminated on June 4, 2026, because its charter was not renewed on or before that expiration date while administrative review remained pending. It is now being reestablished after receiving concurrence from GSA. The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises and informs the Commissioner or designee(s) about the existing and relevant evidence concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases. The Committee may consider the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of at least six voting members including the Chair. Subject to legal and regulatory requirements, members and the Chair are selected by and serve at the discretion of the Commissioner or designee. Each member, including the Chair, will be selected from among authorities knowledgeable in the fields of neurology, pediatric neurology, epidemiology, statistics, and related specialties.

Members will be invited to serve for terms of up to four years, or for less time at the discretion of the Commissioner or designee. Non-Federal members of this committee will serve either as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios.

In addition to the voting members, the Commissioner or designee may identify consumer and/or industry representatives to join the Committee (or serve as alternate representatives) as non-voting representative member(s), via a process consistent with legal and regulatory requirements. Individuals currently employed at FDA-regulated companies, such as pharmaceutical and medical device manufacturers, shall not be selected to serve as members of the Committee unless this Committee is expected to address issues for which inclusion of an industry representative is required by statute. If this Committee includes an industry representative, the Commissioner or designee will determine whether to invite them to participate in meetings on a case-by-case basis, according to applicable legal and regulatory requirements.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees to serve temporarily as voting members and to designate Special Government Employees to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking.

A quorum for the Committee is a majority of the current voting members present at the time, provided that FDA may specify a quorum that is less than a majority of the current voting members because of the size of the

Committee and the variety in the types of issues that it will consider, or other reason determined appropriate in accordance with legal and regulatory requirements. 21 CFR 14.22(d).

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Members appointed to an advisory committee serve for the duration of the committee, or until their terms expire, they resign, or they are removed from membership by the Commissioner or designee. Committee members' terms may be ended prior to their date of expiration, for reasons determined to be good cause. Good cause includes excessive absenteeism from committee meetings, a demonstrated bias that interferes with the ability to render objective advice, failure to abide by established procedures, or violation of other applicable rules and regulations.

This notice of reestablishment also serves as notice under 21 CFR 10.19 that the Commissioner has determined that it is appropriate to waive the provisions of 21 CFR 14.80(e) as they apply to the termination of the current Committee members' terms because the lapse in the Committee charter was an administrative error, the Committee is still needed, and the current membership meets applicable requirements.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/human-drug-advisory-committees/peripheral-and-central-nervous-system-drugs-advisory-committee* or by contacting the Advisory Committee Oversight and Management Staff (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

Reestablishment Requirements and Justification: The Commissioner has determined that reestablishment of the Peripheral and Central Nervous System Drugs Advisory Committee is in the public interest. This determination is based on the Committee's essential role in providing independent expert advice on neurological disease products for which the Food and Drug Administration has regulatory responsibility, the continued need for specialized expertise in this therapeutic area, and the Committee's demonstrated value in supporting FDA's regulatory mission. The following information supports this determination in accordance with applicable legal and regulatory requirements.

Public Interest Determination

Pursuant to 41 CFR 102–3.60(a), to establish, renew, reestablish, or merge a discretionary (agency discretion) advisory committee, an agency must first consult with the General Services Administration's Committee Management Secretariat (the Secretariat) and, as part of the consultation, provide a written public interest determination approved by the head of the agency to the Secretariat with a copy to the Office of Management and Budget. In addition, pursuant to 41 CFR 102–3.35, an agency shall follow the same consultation process and document in writing the same determination of need before creating a subcommittee under a discretionary committee that is not made up entirely of members of a parent advisory committee.

Information on the following factors for the committee is provided to the Secretariat to demonstrate that reestablishing the committee is in the public interest:

1. Annual budget.

Annual budget and expected costs: $90,142.

a. Federal personnel on a full-time equivalent (FTE) basis: The estimated person years of Federal staff support required is 0.25 at an estimated annual cost of $51,384.

b. Other Federal internal costs: The anticipated total value in dollars of other internal costs, such as costs associated with IT and supplies for meetings, is $20,473.

c. Proposed payments to members: The estimated annual payment to members is $4,468.

d. Proposed number of members: The anticipated number of members is 6.

e. Reimbursable costs: The estimated annual reimbursable costs, including travel and related expenses for members, is $6,504.

2. If applicable, the total dollar value of grants expected to be recommended during the fiscal year: N/A.

3. Criteria for selecting members to ensure the committee has the necessary expertise and fairly balanced membership: Ensuring Necessary Expertise: Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of neurology, pediatric neurology, epidemiology, statistics, and related specialties. Nominees should be acknowledged experts with demonstrated skills in critical evaluation of data and effective communication. Members must have background, education, and experience commensurate with the committee's function of advising FDA on the existing and relevant evidence of benefits and risks of marketed and investigational human drug products. Scientific and technical competence is critical. FDA also follows the requirements in section 505(n)(3) regarding membership of drug product advisory committees. (21 U.S.C. 355(n)(3)).

Ensuring Fair Balance: Appointments are made without discrimination. The committee is reviewed in totality for balance, characterized by inclusion of necessary knowledge, insight, and scientific perspective from the relevant community or expertise area. Nominations are sought from all geographic locations within the United States and its territories, and from diverse sources including professional and scientific societies, academia, government agencies, industry and trade associations, consumer and patient organizations, and current Agency staff.

4. List of all other Federal advisory committees of the agency:

FDA maintains the following Federal advisory committees:

- Anesthetic and Analgesic Drug Products Advisory Committee
- Antimicrobial Drugs Advisory Committee
- Blood Products Advisory Committee
- Cardiovascular and Renal Drugs Advisory Committee
- Cellular Tissue and Gene Therapies Advisory Committee
- Dermatologic and Ophthalmic Drugs Advisory Committee
- Device Good Manufacturing Practice Advisory Committee
- Digital Health Advisory Committee
- Drug Safety and Risk Management Advisory Committee
- Endocrinologic and Metabolic Drugs Advisory Committee
- Genetic Metabolic Diseases Advisory Committee
- Medical Devices Advisory Committee
- National Mammography Quality Assurance Advisory Committee (Administratively Inactive)
- Nonprescription Drugs Advisory Committee
- Obstetrics, Reproductive and Urologic Drugs Advisory Committee
- Oncologic Drugs Advisory Committee
- Pediatric Advisory Committee
- Pharmacy Compounding Advisory Committee
- Psychopharmacologic Drugs Advisory Committee
- Pulmonary-Allergy Drugs Advisory Committee
- Risk Communication Advisory Committee (Administratively Inactive)
- Science Board to the Food and Drug Administration
- Technical Electronic Product Radiation Safety Standards Committee
- Tobacco Products Scientific Advisory Committee
- Vaccines and Related Biological Products Advisory Committee

5. Justification that the information or advice provided by the Federal advisory committee or subcommittee is not available from another Federal advisory committee, another Federal Government source, or any other more cost-effective and less burdensome source:

The Committee advises and informs the Commissioner or designee(s) about the existing and relevant evidence concerning the safety and effectiveness of marketed and

investigational human drug products for use in the treatment of neurologic diseases.

The topics considered by the Peripheral and Central Nervous System Drugs Advisory Committee require specialized expertise in the practice of neurology, pediatric neurology, epidemiology, statistics, and other related specialties that is not within the primary scope of other FDA advisory committees. Potential topics that may need committee input include products related to the topics outlined in Section (6) below. These and other issues cannot be appropriately addressed by another standing committee without diminishing the depth and relevance of the expert input provided to the Agency.

6. If the consultation is a committee renewal, a summary of the previous accomplishments of the committee and the reasons it needs to continue:

Summary of Previous Accomplishments:

In 2024, the Peripheral and Central Nervous System Drugs Advisory Committee held one meeting:

June 10, 2024: Discuss biologics license application 761248, for donanemab solution for intravenous infusion, submitted by Eli Lilly and Co., for the treatment of early symptomatic Alzheimer's disease.

In 2023, the Peripheral and Central Nervous System Drugs Advisory Committee held three meetings:

March 22, 2023: Discussed new drug application (NDA) 215887, for tofersen (BIIB067) intrathecal injection, submitted by Biogen Inc., for the treatment of amyotrophic lateral sclerosis (ALS) associated with a mutation in the superoxide dismutase 1 (SOD1) gene.

April 14, 2023 (joint meeting with the Psychopharmacologic Drugs Advisory Committee): Discussed supplemental new drug application (sNDA) 205422 s009, efficacy supplement for REXULTI (brexpiprazole) tablets, submitted by Otsuka Pharmaceutical Company, Ltd., and Lundbeck, Inc., for the proposed treatment of agitation associated with Alzheimer's dementia.

June 9, 2023: Discussed supplemental biologics license application (sBLA) 761269/s–001, for LEQEMBI (lecanemab) solution for intravenous infusion, submitted by Eisai, Inc., for the treatment of Alzheimer's disease, initiated in patients with mild cognitive impairment or mild dementia stage of disease.

7. Explanation of why the committee/subcommittee is essential to the conduct of agency business:

The Committee plays a critical role in enabling FDA to meet the requirements of section 505(n)(1) and (s)(1) of the Federal Food, Drug, and Cosmetic Act by providing expert scientific advice and recommendations. The Peripheral and Central Nervous System Drugs Advisory Committee is the only FDA advisory committee that provides specialized expertise in neurology, pediatric neurology, epidemiology, statistics, and other related specialties. Without the Peripheral and Central Nervous System Drugs Advisory Committee, FDA's ability to obtain external input on issues related to the approval and regulation of neurological products would be significantly limited.

In conclusion, this public interest determination documents that reestablishing the committee is in the public interest, essential to the conduct of agency business, and that the information to be obtained is not already available through another advisory committee or source within the Federal Government.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 *et seq.*). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14829 Filed 7–22–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people living with the disease and their caregivers. During the third meeting of 2026, the Advisory Council will hear from a panel organized by the research subcommittee; updates from federal agencies, including an overview of the authorities of the National Institutes of Health, the Food and Drug Administration, and the Centers for Medicare & Medicaid Services; legislative updates from advocacy groups; and an update on the Robotic-Enabled Microsurgical Intervention for Neurodegenerative Disease (REMIND) Study. Advisory Council subcommittees will also present their recommendations for adoption by the full Advisory Council.

DATES: The meeting will be held on Monday, August 3, 2026, from 10:00 a.m. to 5:00 p.m.

ADDRESSES: The meeting will be a hybrid of in-person and virtual and will be held in the Great Hall of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. It will also stream live at *www.hhs.gov/live*.

FOR FURTHER INFORMATION CONTACT: Maria-Theresa Okafor, 771–223–7102, *maria-theresa.okafor@hhs.gov*. Note: The meeting will be available to the public live at *www.hhs.gov/live*.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: Alzheimer's disease and related dementias, research and innovation, legislative updates, and council recommendations.

Procedure and Agenda: The meeting will be webcast at *www.hhs.gov/live* and video recordings will be added to the National Alzheimer's Project Act website [1] when available after the meeting. This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. Participants joining in person should note that seating may be limited. Those wishing to attend the meeting in person must send an email to *napa@hhs.gov* and put ''August Meeting Attendance'' in the subject line by Monday, July 27 so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email. Please note that individuals entering HHS owned, leased, or operated facilities must present a REAL ID compliant credential or another federally approved form of identification. Below is the list of acceptable forms of ID.

- State-issued Enhanced Driver's License.
- U.S. passport.[2]
- U.S. passport card.[3]
- DHS trusted traveler cards (Global Entry, NEXUS, SENTRI, FAST).
- U.S. Department of Defense ID, including IDs issued to dependents.
- Permanent resident card.
- Border crossing card.

[1] *https://aspe.hhs.gov/collaborations-committees-advisory-groups/napa*

[2] *https://travel.state.gov/content/travel/en/passports.html.*

[3] *https://travel.state.gov/content/travel/en/passports/need-passport/card.html.*