2025 Current Fiscal Year Report: Peripheral and Central Nervous System Drugs Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2025

3. Committee or Subcommittee	3b. GSA Committee No.
Peripheral and Central Nervous System Drugs Advisory Committee	990

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	06/04/2024	06/04/2026	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports	No Reports for this FiscalYear

17a. Open	17b. Closed	17c. Partially Closed	Other Activities	17d. Total
0	0	0	0	0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$0.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$0.00	$0.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	$0.00	$0.00
18d. Other (all other funds not captured by any other cost category)	$0.00	$0.00
18e. Total Costs	$0.00	$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of neurological diseases and makes recommendations to the Commissioner of the Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in the fields of neurology, pediatric neurology, epidemiology, statistics, and related specialties. The Committee has one technically qualified member identified with consumer interests. In addition to the voting members, the Committee includes one non-voting member who is identified with industry interests.

20c. How frequent and relevant are the Committee Meetings?

The Committee did not meet during FY-25. It is expected that the Committee will meet 1-2 times during FY-26.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the Committee are drawn from academia, research, and/or clinical practice. They provide advice and input that FDA considers as part of its regulatory decision-making. The means of obtaining this advice would involve the recruitment of large numbers of scientists on a full-time basis at maximum rates of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?

The Committee held no closed meetings during FY-25.

21. Remarks

There were no reports required for this Committee in FY-25. Although this Committee did not meet in FY-25, considerable time was devoted to appointing members, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was spent in the routine care and maintenance of the

Committee: the development of a financial report for this website; updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members and providing ethics training. Since the Committee did not meet, no reporting was required. Although the current charter states that the Committee shall hold meetings approximately 1-2 times a year, this is only an estimation based on data from previous years. As the FDA convenes advisory committees regarding based on the needs of the Agency, it should not be construed as an exact figure.

Designated Federal Officer

Jessica Seo Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Alexander, Robert	12/01/2021	01/31/2026	Chief Scientific Officer Alzheimer's Prevention Initiative, Banner Alzheimer's Institute; Research Professor, Department of Psychiatry University of Arizona College of Medicine – Phoenix	Special Government Employee (SGE) Member
Apostolova, Liana	12/01/2021	01/31/2026	Distinguished Professor in Neurology, Barbara and Peer Baekgaard Chair in Alzheimer's Disease Research, Indiana University School of Medicine	Special Government Employee (SGE) Member

Cudkowicz, Merit	12/01/2021	01/31/2025	Julieanne Dorne Professor of Neurology, Harvard Medical School; Chair, Department of Neurology, Director, Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital	Special Government Employee (SGE) Member
Kirsch, Paul	01/17/2024	10/31/2027	Vice President, Regulatory Affairs, Harmony Biosciences, LLC	Representative Member
Kryscio, Richard	05/09/2024	01/31/2026	Professor, Statistics and Biostatistics ,University of Kentucky Sanders-Brown Center on Aging	Special Government Employee (SGE) Member
Montine, Thomas	12/01/2021	01/31/2026	Chair, Department of Pathology, Stanford Medicine Endowed Professor, Stanford University School of Medicine	Special Government Employee (SGE) Member
Simuni, Tanya	05/25/2024	01/31/2028	Arthur C. Nielsen Professor of Neurology, Division Head, Parkinson's Disease and Movement Disorders Center, Northwestern University Feinberg School of Medicine	Special Government Employee (SGE) Member
Weisman, David	05/09/2024	01/31/2028	Distinguished Professor in Neurology, Barbara and Peer Baekgaard Chair in Alzheimer's Disease Research, Indiana University School of Medicine	Special Government Employee (SGE) Member

Number of Committee Members Listed: 8

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Peripheral and Central Nervous System Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases and makes recommendations to the Commissioner of Food and Drugs. This advice supports the FDA in its regulatory decision-making regarding new medical technologies and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of the public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	☑
Trust in government	☑
Major policy changes	☑
Advance in scientific research	☑
Effective grant making	☐
Improved service delivery	☐
Increased customer satisfaction	☑
Implementation of laws or regulatory requirements	☑
Other	☐

Outcome Comments

N/A

What are the cost savings associated with this committee?

	Checked if Applies
None	☐
Unable to Determine	☑
Under $100,000	☐
$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments

The utilization of the Peripheral and Central Nervous System Drugs Advisory Committee enabled the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

33

Number of Recommendations Comments

The Committee made 33 recommendations from FY-03 through FY-25.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

84%

% of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, therefore, the Agency has the option of not implementing the advice. This number represents an approximation of the percentage of recommendations that the agency has fully implemented or plans to fully implement.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

10%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☑
Issued new regulation	☑
Proposed legislation	☑
Approved grants or other payments	☐
Other	☑

Action Comments

FDA approves or chooses not to approve new medical products.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

Checked if Applies

Contact DFO	☑
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☑
Other	☐

Access Comments

N/A