2025 Current Fiscal Year Report: Pharmaceutical Science and Clinical Pharmacology Advisory Committee

Report Run Date: 04/24/2026 08:33:23 PM

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

3. Committee or Subcommittee	3b. GSA Committee No.
Pharmaceutical Science and Clinical Pharmacology Advisory Committee	878

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	01/22/2024	01/22/2026	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
Yes	2025 Secretary Directive	04/01/2025

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Terminate	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	$12,821.00	$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)	$3,205.00	$0.00
18e. Total Costs	$16,026.00	$0.00
19. Federal Staff Support Years (FTE)	0.10	0.00

20a. How does the Committee accomplish its purpose?

The Committee shall provide advice on scientific, clinical and technical issues related to safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have and as

required, any other product for which the Food and Drug Administration has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are selected from academic, research and practice settings and include researchers knowledgeable in the fields of biostatistics, bioavailability, clinical pharmacology, pharmacokinetics, pharmaceutics, industrial pharmacy, statistics, biopharmaceutics, and other related professions. The Committee included one technically qualified voting member who is identified with consumer interests. The Committee may also include three non-voting members who are identified with industry interests. There may also be an alternate industry representative.

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

The Committee did not meet during FY-25.

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 decisions. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientists on a full-time basis at a maximum rate 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

2025 Secretary Directive-Elimination of Federal Advisory Committees Within the Department of Health and Human Services, Terminated 04.01.2025. 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 based on the needs of the Agency, it should not be construed as an exact figure.

Designated Federal Officer

Michael Gu Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Beringer, Paul	11/01/2018	04/01/2025	Professor and Chair, Department of Clinical Pharmacy, University of Southern California, School of Pharmacy	Special Government Employee (SGE) Member
Carrico, Jeffery	12/30/2015	10/31/2024	Director, Research Pharmacy, Department of Pharmacy, Dana-Farber Cancer Institute	Special Government Employee (SGE) Member

Dutta, Sandeep	04/29/2024	04/01/2025	Vice President, Global Clinical Development and Global Head, Amgen	Representative Member
Finestone, Sandra	11/01/2017	04/01/2025	CONSUMER REPRESENTATIVE; Executive Director, Association of Cancer Patient Educators	Special Government Employee (SGE) Member
Girgis, Suzette	04/30/2024	04/01/2025	Vice President and Head Global Clinical Pharmacology & Pharmacometrics, Jazz Pharmaceuticals	Representative Member
Kagan, Leonid	11/01/2021	04/01/2025	Associate Professor, Department of Pharmaceutics, Ernest Mario School of Pharmacy, Rutgers, The State University of New Jersey	Special Government Employee (SGE) Member
Kraft, Walter	11/01/2018	04/01/2025	Professor of Pharmacology, Medicine & Surgery, Department of Pharmacology, Physiology, & Cancer Biology, Thomas Jefferson University	Special Government Employee (SGE) Member
Morris, Kenneth	11/01/2018	04/01/2025	Professor Emeritus of Pharmaceutical Sciences, University of Hawaii at Hilo	Special Government Employee (SGE) Member
Richmond, Frances	09/27/2018	04/01/2025	Director, D K Kim International Center for Regulatory Science, Department of Regulatory and Quality Sciences, School of Pharmacy, University of Southern California	Special Government Employee (SGE) Member
Rothe, Pravin	11/01/2019	04/01/2025	Advisor - EGQCA, ELANCO	Representative Member
Slud, Eric	03/08/2019	04/01/2025	Area Chief for Mathematical Statistics, Center for Statistical Research and Methodology, Census Bureau	Regular Government Employee (RGE) Member

Zamboni, William	01/13/2025	04/01/2025	Professor, University of North Carolina	Special Government Employee (SGE) Member

Number of Committee Members Listed: 12

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 Pharmaceutical Science and Clinical Pharmacology Advisory Committee supports FDA's strategic priorities by reviewing and evaluating data on scientific and technical issues concerning the safety, and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases, and as required, any other product for which the Food and Drug Administration has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's generic drug regulatory responsibilities. This supports the development of safe and effective 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 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 Pharmaceutical Science and Clinical Pharmacology Advisory Committee enabled the Agency to obtain required and frequently scarce services from medical and scientific experts not otherwise available to the Agency; and to obtain the services from 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?

147

Number of Recommendations Comments

The Committee made 147 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 or issues are available publicly when implemented https://www.fda.gov/advisory-committees

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 an investigational new medical product.

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