2024 Current Fiscal Year Report: Pharmaceutical Science and Clinical Pharmacology Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2024

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	01/22/2022	01/22/2024	

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. Other(rents,user charges, graphics, printing, mail, etc.)	$0.00	$0.00
18d. Total	$0.00	$0.00
19. Federal Staff Support Years (FTE)	0.00	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 four non-voting members who are identified with industry interests.

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

In FY-23, the Committee held 1 meeting. On November 2-3, 2022, the Pharmaceutical Science and Clinical Pharmacology Products Advisory Committee discussed two topics related to the Office of Pharmaceutical Quality's mission of promoting the availability of quality medicines for the American public. On November 2, 2022, the committee discussed the Center for Drug Evaluation and Research (CDER) Quality Management Maturity (QMM) program. QMM is the state attained when drug manufacturers have consistent, reliable, and robust business processes to achieve quality objectives and promote continual improvement. CDER has proposed the development of a rating system that will help incentivize drug manufacturers to adopt more mature quality management practices at their facilities. The committee considered the impact that a QMM program would have on the pharmaceutical industry, drug shortages, and supply chain resiliency. FDA sought input to determine if experts from academia and industry support the development of a CDER QMM

program to incentivize investments in mature quality management practices. On November 3, 2022, as part of CDER's continued effort to provide key updates on modernization of quality assessment, the committee discussed the next stages of Knowledge-Aided Assessment and Structured Application (KASA). The concept of KASA was envisioned in 2016 and discussed at the Pharmaceutical Science and Clinical Pharmacology Advisory Committee (PSCP-AC) meeting on September 20, 2018 as an IT system that modernizes FDA's assessment. Through the development, testing, and implementation of various KASA prototypes, the KASA system has been refined over the course of multiple years. FDA sought input on the vision and plan to expand KASA over the next five years to include drug substances, all generic dosage forms, new drug and biologics applications, and post-approval changes. Moreover, FDA sought input regarding the need for advancing digitalization in KASA, including data standardization and mobilization of data from cloud-based servers. On November 2nd, a majority of members (9 Yeses and 0 Noes) voted that CDER should establish a QMM program to incentivize investments in mature quality management practices. On November 3rd, majority of members (13 Yeses and 0 Noes) supported the long-term strategy for developing and implementing KASA at FDA and expanding the system from generic drugs to new drugs and biologics assessments. Agency Action: The Agency is reviewing recommendations made at the meeting. It is expected that the Committee will meet once in FY-24.

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. Their advice and input lends credibility to FDA regulatory decisions. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientist 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-23.

21. Remarks

Designated Federal Officer

Rhea Bhatt DFO

Committee Members	Start	End	Occupation	Member Designation
Beringer, Paul	11/01/2018	10/31/2026	Professor and Chair, University of Southern California, School of Pharmacy	Special Government Employee (SGE) Member
Carrico, Jeffery	12/30/2015	10/31/2024	Professor of Pharmacology, Thomas Jefferson University	Special Government Employee (SGE) Member
Finestone, Sandra	11/01/2017	10/31/2025	CONSUMER REPRESENTATIVE; Executive Director, Association of Cancer Patient Educators	Special Government Employee (SGE) Member
Kagan, Leonid	11/01/2021	10/31/2025	Associate Professor, Department of Pharmaceutics, Ernest Mario School of Pharmacy, Rutgers, The State University of New Jersey	Special Government Employee (SGE) Member
Kibbe, Arthur	01/23/2020	10/31/2023	Emeritus Professor, Wilkes University, Nesbitt School of Pharmacy	Special Government Employee (SGE) Member

Kraft, Walter	11/01/2018	10/31/2026	Professor of Pharmacology and Experimental Therapeutics, Thomas Jefferson University	Special Government Employee (SGE) Member
Lee, Kelvin	01/23/2020	10/31/2023	Gore Professor, Chemical & Biomolecular Engineering, University of Delaware	Special Government Employee (SGE) Member
Morris, Kenneth	11/01/2018	10/31/2026	Professor Emeritus of Pharmaceutical Sciences, University of Hawaii at Hilo	Special Government Employee (SGE) Member
Richmond, Frances	09/27/2018	10/31/2025	Professor and Director, D K Kim International Center for Regulatory Science	Special Government Employee (SGE) Member
Rogge, Mark	11/01/2019	10/31/2023	Chief Development Officer, Sail Bio, Inc.	Representative Member
Rothe, Pravin	11/01/2019	10/31/2023	Validation Lead, Manufacturing Sciences and Technology, Novartis	Representative Member
Slud, Eric	03/08/2019	10/31/2025	Area Chief for Mathematical Statistics, Census Bureau	Regular Government Employee (RGE) Member
Venkateshwaran, T	11/01/2019	10/31/2023	Vice President and Global Head, Global Regulatory Affairs – CMC and Devices, Takeda	Representative Member
Zamboni, William	01/25/2022	10/31/2024	Professor, Division of Pharmacotherapy and Experimental Therapeutics, UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill	Special Government Employee (SGE) Member

Number of Committee Members Listed: 14

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-23.

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
It usually does. Product approval issues are first released to the sponsor. 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 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