2025 Current Fiscal Year Report: Drug Safety and Risk Management 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.
Drug Safety and Risk Management Advisory Committee	847

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	05/31/2024	05/31/2026	

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 information on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs

regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances.

20b. How does the Committee balance its membership?

Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is 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-24. It is expected that the Committee will meet 3 times or more 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. Their advice and input is considered as part of FDA's regulatory decision-making and helps those decisions stand up to intense public scrutiny. The alternate means of obtaining this advice would be to hire large numbers of scientists on a full time basis at a great expense to the government.

20e. Why is it necessary to close and/or partially closed committee meetings?
The committee held no closed meetings during FY-24.

21. Remarks
Although this Committee did not meet in FY-24, 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 3-6 times a year, this is only an estimate 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
Moon Choi Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Dejos, Michael	09/20/2023	05/31/2027	System Medication Safety Officer, Methodist Le Bonheur Healthcare, Assistant Professor, University of Tennessee Health Science Center	Special Government Employee (SGE) Member
Dublin, Sascha	06/01/2022	05/31/2026	Senior Scientific Investigator, Kaiser Permanente Washington Health Research Institute	Special Government Employee (SGE) Member
Floyd, James	06/01/2022	05/31/2026	Associate Professor of Medicine, Adjunct Professor of Epidemiology, University of Washington	Special Government Employee (SGE) Member
Hertig, John	06/01/2021	05/31/2025	Associate Professor and Vice Chair, Department of Pharmacy Practice, Butler University College of Pharmacy and Health Sciences	Special Government Employee (SGE) Member
Huybrechts, Krista	06/01/2021	05/31/2025	Associate Professor of Medicine and Epidemiology, Harvard Medical School and Harvard T.H. Chan School of Public Health, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital	Special Government Employee (SGE) Member
Liu, Tao	06/01/2022	05/31/2026	Associate Professor of Biostatistics, Brown University	Special Government Employee (SGE) Member
Lo Re, Vincent	06/01/2021	05/31/2025	Associate Professor of Epidemiology and Medicine, Center for Clinical Epidemiology and Biostatistics, Center for Pharmacoepidemiology Research and Training, Perelman School of Medicine, University of Pennsylvania	Special Government Employee (SGE) Member

McAdams DeMarco, Mara	06/01/2021	05/31/2025	Associate Professor, Associate Vice Chair for Research, Department of Surgery, New York University	Special Government Employee (SGE) Member
Rodriguez, Ignacio	06/11/2024	10/31/2027	Vice President, Global Head Medical Safety, Novartis Pharmaceuticals Corporation	Representative Member

Number of Committee Members Listed: 9

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 Drug Safety and Risk Management Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility and making appropriate recommendations to the Commissioner of Food and Drugs. The Committee also advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances. 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 Drug Safety and Risk Management Drugs Advisory Committee enabled the Agency to obtain required and frequently scarce external input 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?
75

Number of Recommendations Comments
The Committee made 75 recommendations from FY-03 through FY-24.

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. Please see https://www.fda.gov/.

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 or other regulatory decision-making.

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