

2025 Current Fiscal Year Report: Psychopharmacologic Drugs Advisory Committee

Report Run Date: 06/13/2025 02:12:12 AM

1. Department or Agency

Department of Health and Human
Services

2. Fiscal Year

2025

3. Committee or Subcommittee

Psychopharmacologic Drugs Advisory
Committee

3b. GSA

Committee No.

1009

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 Fiscal Year?

8b. Specific Termination Authority

8c. Actual Term Date

No

9. Agency Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

Not Applicable

10b. Legislation Pending?

Not Applicable

11. Establishment Authority

Authorized by Law

12. Specific Establishment Authority

21 U.S.C. 394

13. Effective Date

11/28/1990

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee

Scientific Technical Program
Advisory Board

16a. Total Number of Reports

No Reports for
this Fiscal Year

17a. Open 0

17b. Closed 0

17c. Partially Closed 0

Other Activities 0

17d. Total 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 reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the practice of psychiatry and other related fields and makes recommendations to the Commissioner of Food and Drugs.

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

psychopharmacology, psychiatry, epidemiology or 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?

In FY-24, the committee held one meeting. On June 4, 2024, the Committee met to discuss new drug applications (NDA) 215455, for Midomafetamine (MDMA) capsules, submitted by Lykos Therapeutics, for proposed treatment of post-traumatic stress disorder. The committee was asked to discuss if the benefits of midomafetamine with FDA's proposed risk evaluation and mitigation strategy (REMS) outweigh its risks for treatment of patients with PTSD. The majority of the committee (10 yeses and 1 no) agreed that the benefits of midomafetamine with FDA's REMS did not outweigh its risks for the treatment of patients with PTSD. It is expected that the Committee will meet 1-3 times 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 by FDA as part of its regulatory decision-making, which helps those decisions stand up to intense public scrutiny. 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-24.

21. Remarks

There were no reports required for this Committee in FY-24. Although the current charter states that the Committee shall hold meetings approximately 1-3 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

Joyce Frimpong Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Baladi, Michelle	02/15/2024	10/31/2027	Executive Director, Clinical Development Neuroscience, Jazz Pharmaceuticals	Representative Member
Canuso, Carla	02/15/2024	10/31/2027	CONSUMER REPRESENTATIVE Vice President, Head of Neuropsychiatry Clinical Development, LLC	Special Government Employee (SGE) Member
Dunn, Walter	08/25/2021	06/30/2025	Assistant Clinical Professor, West Los Angeles VA Medical Center, UCLA Dept of Psychiatry	Regular Government Employee (RGE) Member
Fiedorowicz, Jess	08/25/2021	06/30/2025	Assistant Professor of Psychiatry, Associate Director, Division of Population Behavioral Health, UCLA	Special Government Employee (SGE) Member
Narendran, Rajesh	08/25/2021	06/30/2025	Attending Psychiatrist, Resolve Crisis Services, UPMC Western Psychiatric Hospital	Special Government Employee (SGE) Member

Thomas, Patrick	08/30/2022 06/30/2026	Assistant Professor of Psychiatry, Baylor College of Medicine, Menninger Clinic	Special Government Employee (SGE) Member
--------------------	-----------------------	---	---

Number of Committee Members Listed: 6

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 Psychopharmacologic 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 practice of psychiatry and related fields and makes appropriate recommendations to the Commissioner of Food and Drugs. 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	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input checked="" type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input type="checkbox"/>

- | | |
|---|-------------------------------------|
| Increased customer satisfaction | <input checked="" type="checkbox"/> |
| Implementation of laws or regulatory requirements | <input checked="" type="checkbox"/> |
| Other | <input type="checkbox"/> |

Outcome Comments

NA

What are the cost savings associated with this committee?

Checked if Applies

- | | |
|----------------------------|-------------------------------------|
| None | <input type="checkbox"/> |
| Unable to Determine | <input checked="" type="checkbox"/> |
| Under \$100,000 | <input type="checkbox"/> |
| \$100,000 - \$500,000 | <input type="checkbox"/> |
| \$500,001 - \$1,000,000 | <input type="checkbox"/> |
| \$1,000,001 - \$5,000,000 | <input type="checkbox"/> |
| \$5,000,001 - \$10,000,000 | <input type="checkbox"/> |
| Over \$10,000,000 | <input type="checkbox"/> |
| Cost Savings Other | <input type="checkbox"/> |

Cost Savings Comments

The utilization of the Psychopharmacologic 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; an 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?

39

Number of Recommendations Comments

The Committee made 39 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 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	<input checked="" type="checkbox"/>
Reallocated resources	<input checked="" type="checkbox"/>
Issued new regulation	<input checked="" type="checkbox"/>
Proposed legislation	<input checked="" type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

Action Comments

Recommendation: 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

NA

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