

2025 Current Fiscal Year Report: Psychopharmacologic 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.
Psychopharmacologic Drugs Advisory Committee	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	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. Committee 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 Fiscal Year

17a. Open 2 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 2

Meetings and Dates

Purpose	Start	End
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The Committees discussed the reevaluation of the Clozapine Risk Evaluation and Mitigation Strategy (REMS) and possible changes to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of clozapine. 11/19/2024 - 11/19/2024

The Committee discussed supplemental New Drug Application (sNDA) 205422/S-012, for REXULTI (brexpiprazole) tablets, submitted by Otsuka Pharmaceutical Company, Ltd., for the proposed indication of treatment of adults with post-traumatic stress disorder (PTSD), in combination with sertraline. 07/18/2025 - 07/18/2025

Number of Committee Meetings Listed: 2

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$6,240.00	\$17,472.00
18a(2). Personnel Pmts to Federal Members	\$2,496.00	\$2,496.00
18a(3). Personnel Pmts to Federal Staff	\$190,783.00	\$50,372.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$7,760.00	\$21,857.00
18b(2). Travel and Per Diem to Federal Members	\$3,554.00	\$3,577.00
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)	\$56,677.00	\$21,666.00
18e. Total Costs	\$267,510.00	\$117,440.00
19. Federal Staff Support Years (FTE)	1.10	0.25

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 may include one non-voting member who is identified with industry interests.

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

In FY-25, the committee held two meetings. At one of these meetings, the Committee met in joint session with other Committees but was not the lead Committee. See the Agency Recommendations, Remarks section for a list of joint meetings in which the Committee was not the lead Committee. On November 19, 2024, a

meeting was held jointly with the Drug Safety and Risk Management Advisory Committee. Further information regarding this meeting is provided in the Recommendation Remarks section. On July 18, 2025, the Committee met to discuss supplemental New Drug Application (sNDA) 205422/S-012, for REXULTI (brexpiprazole) tablets, submitted by Otsuka Pharmaceutical Company, Ltd., for the proposed indication of treatment of adults with post-traumatic stress disorder (PTSD), in combination with sertraline. The committee was asked to discuss if with the available data presented, had the efficacy of brexpiprazole, when initiated concurrently with sertraline, been established for the treatment of PTSD. The majority of the committee (10 yeses and 1 no) agreed that the current evidence did not establish efficacy for the treatment of PTSD. It is expected that the Committee will meet 1-3 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. 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 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

There were no reports required for this Committee in FY-25. In FY-25, the Committee held two meetings. At one of these meetings, the Committee met in joint session with other committees but was not the lead Committee. So that joint meetings are not counted twice in the FACA database, they will be reported under the primary or lead Committee. For the purposes of this database, the secondary Committee still reports meeting information and costs associated under this section of the report as well as the cost section. On November 19, 2024, the Drug Safety and Risk Management Advisory Committee and the Psychologic Drugs Advisory Committee met jointly to discuss the reevaluation of the Clozapine Risk Evaluation and Mitigation Strategy (REMS) and possible changes to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of clozapine. The issues the Committees discussed included whether clozapine healthcare providers have sufficient knowledge and access to resources about the risk of neutropenia and need for absolute neutrophil count (ANC) monitoring, and whether ANC monitoring would be performed without the requirements of the REMS. The Committees were in near unanimous agreement (14 Noes and 1 Yes) that the following REMS requirements are not necessary to ensure safe use of clozapine: documentation of ANC results by providers and verification of those results by pharmacies, and requirements for education of healthcare providers about the risk of severe neutropenia and need for ANC monitoring. Agency Action: As of February 24, 2025, the Agency no longer expects prescribers, pharmacies, and patients to participate in the REMS program for clozapine or to report results of absolute neutrophil count (ANC) blood tests before pharmacies dispense

clozapine. FDA still recommends that prescribers monitor patients' ANC according to the monitoring frequencies described in the prescribing information. On July 18, 2025, the Committee met to discuss supplemental New Drug Application (sNDA) 205422/S-012, for REXULTI (brexpiprazole) tablets, submitted by Otsuka Pharmaceutical Company, Ltd., for the proposed indication of treatment of adults with post-traumatic stress disorder (PTSD), in combination with sertraline. The committee was asked to discuss if with the available data presented, had the efficacy of brexpiprazole, when initiated concurrently with sertraline, been established for the treatment of PTSD. The majority of the committee (10 yeses and 1 no) agreed that the current evidence did not establish efficacy for the treatment of PTSD. Agency Action: The Agency is still reviewing all recommendations that were made at the meeting. The committee chair is vacant at this time.

Designated Federal Officer

Joyce Frimpong Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Ballon, Jacob	07/18/2025	07/18/2025	Associate Professor, Stanford University	Special Government Employee (SGE) Member
Block, Laura	07/18/2025	07/18/2025	Pharmacist	Special Government Employee (SGE) Member
Canuso, Carla	02/15/2024	10/31/2027	Vice President, Head of Neuropsychiatry Clinical Development, LLC	Representative 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
Raskind, Murray	07/18/2025	07/18/2025	Director, Mental Illness Research, Education, and Clinical Center Veteran Affairs Puget Sound Health Care System	Regular Government Employee (RGE) Member
Shiner, Brian	07/18/2025	07/18/2025	Associate Chief of Staff for Research, Veteran Affairs Vermont Healthcare System	Regular Government Employee (RGE) Member
Simon, Gregory	07/18/2025	07/18/2025	Psychiatrist, Kaiser Permanente Washington Health Research	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: 10

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?

41

Number of Recommendations Comments

The Committee made 41 recommendations from FY-03 through FY-25. See Committee website for specific accomplishments:

<https://www.fda.gov/advisory-committees/human-drug-advisory-committees/psychopharmacolog>

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

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