2022 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	2022

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	06/04/2022	06/04/2024	

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
2	0	0	0	2

Meetings and Dates

Purpose	Start	End

The Committee discussed new drug application (NDA) 214812, for carbetocin nasal spray, submitted by Levo Therapeutics, Inc., for the proposed treatment of hyperphagia, anxiety, and distress behaviors associated with Prader-Willi syndrome.	11/04/2021 - 11/04/2021
The Committee discussed supplemental new drug applications 210793-s008 and 207318-s011, efficacy supplement resubmission for NUPLAZID (pimavanserin) tablets, submitted by Acadia Pharmaceuticals Inc., for the proposed treatment of hallucinations and delusions associated with Alzheimer's disease psychosis.	06/17/2022 - 06/17/2022

Number of Committee Meetings Listed: 2

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$9,571.00	$14,134.00
18a(2). Personnel Pmts to Federal Members	$3,378.00	$2,356.00
18a(3). Personnel Pmts to Federal Staff	$181,039.00	$189,742.00
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.)	$56,403.00	$58,692.00

18d. Total	$250,391.00	$264,924.00
19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investgational human drug products for use in the practice of psychiatry and other related fields and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in psychopharmacology, psychiatry, and epidemiology or statistics who are qualified by training and experience to evaluate scientific data. 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-22, the Committee held two meetings. On November 4, 2021, the Committee discussed new drug application (NDA) 214812, for carbetocin nasal spray, submitted by Levo Therapeutics, Inc., for the proposed treatment of hyperphagia, anxiety, and distress behaviors associated with Prader-Willi syndrome. The majority of the Committee members (1 Yeses, 12 Noes) voted “No,” that the Applicant did not provide substantial evidence of effectiveness for carbetocin nasal spray for the treatment of hyperphagia associated with Prader-Willi syndrome. Agency Action: The

FDA is still reviewing recommendations made at this meeting. On June 17, 2022, the Committee discussed supplemental new drug applications 210793-s008 and 207318-s011, efficacy supplement resubmission for NUPLAZID (pimavanserin) tablets, submitted by Acadia Pharmaceuticals Inc., for the proposed treatment of hallucinations and delusions associated with Alzheimer's disease psychosis (ADP). The majority of the Committee members (3 Yeses, 9 Noes) voted “No,” that the available evidence does not support a conclusion that pimavanserin is effective for the treatment of hallucinations and delusions in the ADP population. Agency Action: The FDA is still reviewing recommendations made at this meeting. It is expected that the Committee will meet one to three times in FY-23.

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 regulatory decisions, 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-22.

21. Remarks
There are no reports required for the Committee in FY-22.

Designated Federal Officer

Joyce Frimpong Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Apostolova, Liana	06/17/2022	06/17/2022	Distinguished Professor in Neurology, Barbara and Peer Baekgaard Chair in Alzheimer's Disease Research,Indiana Alzheimer's Disease Center	Special Government Employee (SGE) Member
Baker, Robert	03/27/2020	10/31/2023	Deputy Chief Medical Officer, Vice President, Clinical Program Design and Exploratory Medicine and Pharmacology, Eli Lilly and Company	Representative Member
Billington, Charles	11/04/2021	11/04/2021	Chief, Section of Endocrinology and Metabolism, Minneapolis VA Health Care System	Regular Government Employee (RGE) Member
Cudkowicz, Merit	06/17/2022	06/17/2022	Julieanne Dorn Professor of Neurology Chair, Department of Neurology and Director of the Sean M. Healey and AMG Center for ALS at Mass General Hospital Harvard Medical School	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	Head and Chief, Department of Mental Health The Ottawa Hospital Professor and Senior Research Chair in Adult Psychiatry, Department of Psychiatry University of Ottawa	Special Government Employee (SGE) Member

Follmann, Dean	06/17/2022	06/17/2022	Assistant Director for Biostatistics National Institute of Allergy and Infectious Diseases, NIH	Regular Government Employee (RGE) Member
Iyengar, Satish	07/01/2016	06/30/2024	Chair and Professor of Statistics, University of Pittsburgh	Special Government Employee (SGE) Member
Jeffrey, Jessica	07/01/2016	06/30/2024	Assistant Professor of Psychiatry, Associate Director, Division of Population Behavioral Health, UCLA	Special Government Employee (SGE) Member
Johnston, Colette	06/17/2022	06/17/2022	PATIENT REPRESENTATIVE	Special Government Employee (SGE) Member
Keller, William	08/25/2021	06/30/2025	Assistant Professor in the Department of Psychiatry Dartmouth-Hitchcock Medical Center	Special Government Employee (SGE) Member
Krishna, Sonia	07/01/2020	06/30/2024	Affiliate Faculty, Dell Medical School at The University of Texas at Austin	Special Government Employee (SGE) Member
McGough, James	11/04/2021	11/04/2021	Professor of Clinical Psychiatry, Division of Child and Adolescent Psychiatry David Geffen School of Medicine at 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
Shapley, Alice	11/04/2021	11/04/2021	PATIENT REPRESENTATIVE	Special Government Employee (SGE) Member
Stander, Paul	06/17/2022	06/17/2022	Associate Chief of Staff Geriatrics and Extended Care Phoenix Veterans Affairs Health System	Regular Government Employee (RGE) Member
Thambisetty, Madhav	06/17/2022	06/17/2022	Senior Investigator National Institute on Aging, NIH	Regular Government Employee (RGE) Member

Thomas, Patrick	08/30/2022	06/30/2026	Assistant Professor of Psychiatry, Baylor College of Medicine, Menninger Clinic	Special Government Employee (SGE) Member
Troendle, James	11/04/2021	11/04/2021	Deputy Director, Office of Biostatistics, Research National Heart, Lung, and Blood Institute, NIH	Regular Government Employee (RGE) Member
Witczak, Kim	12/30/2015	06/30/2024	CONSUMER REPRESENTATIVE; Co-Founder, Executive Director, Woodymatters	Special Government Employee (SGE) Member

Number of Committee Members Listed: 20

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	✓
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

NA

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 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?

37

Number of Recommendations Comments
The Committee made 37 recommendations from FY-03 through FY-22.

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.

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