2022 Current Fiscal Year Report: Anesthetic and Analgesic Drug Products 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.
Anesthetic and Analgesic Drug Products Advisory Committee	788

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	05/01/2022	05/01/2024	

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
1	0	0	0	1

Meetings and Dates

Purpose	Start	End

The Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee discussed new drug application (NDA) 213231, for tramadol hydrochloride injection, submitted by Avenue Therapeutics, Inc., for the management of moderate to moderately severe pain in adults in a medically supervised healthcare setting. The issues for the committees to discuss included the clinical relevance of tramadol hydrochloride injection, an opioid intended for management of acute pain in a medically supervised healthcare setting, when its onset of action is delayed, and its proposed dosing is a fixed-dosing regimen.	02/15/2022 - 02/15/2022

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$6,756.00	$28,267.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$189,547.00	$187,929.00
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.)	$50,854.00	$57,489.00

18d. Total	$247,157.00	$273,685.00
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 investigational human drug products including analgesics, e.g., abuse-deterrent opioids, novel analgesics, and issues related to opioid abuse, and those for use in anesthesiology and makes appropriate 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 anesthesiology, analgesics (such as: abuse deterrent opioids, novel analgesics, and issues related to opioid abuse) epidemiology or statistics, and related specialties. 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?

In FY-22, the Committee held one meeting. On February 15, 2022, the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee met jointly to discuss new drug application (NDA) 213231, for tramadol hydrochloride injection, submitted by Avenue Therapeutics, Inc., for the management of moderate to moderately severe pain in adults in a medically supervised healthcare setting. The issues that the Committees discussed included the clinical relevance of tramadol hydrochloride injection, an opioid intended for management of acute pain in a medically supervised healthcare setting, when its onset of action is delayed, and its proposed dosing is a fixed-dosing regimen. A majority of members (8 Yeses and 14 Noes) voted that the Applicant did not submit adequate information to support the position that the benefits for their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting. Agency Action: The Agency is reviewing recommendations made at the meeting. It is expected that the Committee will meet three to five times during 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 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-22.

21. Remarks

There were no reports required for this Committee in FY-22. Although the current charter states that the committee shall hold meetings approximately three to five 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

Moon Hee V. Choi DFO

Committee Members	Start	End	Occupation	Member Designation
Bateman, Brian	04/01/2021	03/31/2025	Professor and Chair; Department of Anesthesiology, Perioperative, and Pain Medicine; Stanford University School of Medicine	Special Government Employee (SGE) Member
Bicket, Mark	04/01/2022	03/31/2026	Assistant Professor, Department of Anesthesiology Co-Director, Opioid Prescribing Engagement Network University of Michigan	Special Government Employee (SGE) Member
Goudra, Basavana	04/01/2018	03/31/2022	Director of Endoscopy Anesthesia Services, Penn Presbyterian Medical Center	Special Government Employee (SGE) Member
Higgins, Jennifer	03/29/2019	03/31/2023	CONSUMER REPRESENTATIVE; Owner, CommonWealth GrantWorks	Special Government Employee (SGE) Member
Horrow, Jay	11/01/2019	10/31/2023	Clinical Lead, Cardiovascular Drug Development, Bristol-Myers Squibb	Representative Member

Jowza, Maryam	04/01/2019	03/31/2023	Associate Professor of Anesthesiology and Pain Management, University of North Carolina-Chapel Hill	Special Government Employee (SGE) Member
McAuliffe, Maura	03/29/2019	03/31/2026	Professor, College of Nursing, East Carolina University	Special Government Employee (SGE) Member
McCann, Mary	04/01/2021	03/31/2025	Associate Professor, Anesthesiology, Critical Care and Pain Medicine, Harvard Medical School, Boston Children's Hospital	Special Government Employee (SGE) Member
Ness, Timothy	04/01/2022	03/31/2024	Professor Emeritus, Department of Anesthesiology and Perioperative Medicine, University of Alabama at Birmingham	Special Government Employee (SGE) Member
O'Brien, Joseph	02/15/2022	02/15/2022	President & CEO, National Scoliosis Foundation	Special Government Employee (SGE) Member
Richmond, Rebecca	04/01/2021	03/31/2025	Associate Chief Pharmacy Officer, Central Pharmacy Services, Duke University Hospital	Special Government Employee (SGE) Member
Ruha, Anne-Michelle	02/15/2022	02/15/2022	Chair, Department of Medical Toxicology, Banner - University Medical Center Phoenix. Professor, Departments of Internal Medicine and Emergency Medicine, University of Arizona College of Medicine - Phoenix	Special Government Employee (SGE) Member
Shoben, Abigail	06/05/2015	03/31/2024	Associate Professor, Ohio State University	Special Government Employee (SGE) Member
Sprintz, Michael	04/01/2019	03/31/2023	Clinical Assistant Professor, Division of Geriatric and Palliative Medicine, University of Texas Health Science Center	Special Government Employee (SGE) Member

Urman, Richard	03/29/2019	03/31/2022	Associate Professor of Anesthesia, Harvard Medical School	Special Government Employee (SGE) Member
Zaafran, Sherif	04/01/2020	03/31/2024	President, Texas Medical Board	Special Government Employee (SGE) Member
Zacharoff, Kevin	02/15/2022	02/15/2022	Faculty and Clinical Instructor; Course Director Pain and Addiction; Department of Family, Population, and Preventive Medicine, Renaissance School of Medicine at Stony Brook, University	Special Government Employee (SGE) Member

Number of Committee Members Listed: 17

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 Anesthetic and Analgesic Drug Products 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 treatment of anesthesia and treatment of pain and makes appropriate recommendations to the Commissioner of Food and Drugs.

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 Anesthetic and Analgesic Drug Products Advisory Committee enables the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed bases 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?

60

Number of Recommendations Comments
The Committee made 60 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 or issues are available publicly when implemented https://www.fda.gov/advisory-committees

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 new medical products.

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