2025 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	2025

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	05/01/2024	05/01/2026	

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
2	0	0	0	2

Meetings and Dates

Purpose	Start	End

The Committee discussed BLA 761393, condoliase injection submitted by Seikagaku Corp., for the proposed indication of the treatment of radicular leg pain associated with confirmed nerve root impingement caused by lumbar disc herniation in adults.	01/10/2025 - 01/10/2025
The Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee met jointly to discuss the findings of the completed extended-release/long-acting opioid analgesic (ER/LA OA) postmarketing requirements (PMRs) 3033-1 and 3033-2 (https://www.fda.gov/media/95546/download). These PMRs are prospective (3033-1) and retrospective (3033-2) epidemiologic studies that examined the serious risks and predictors of misuse, abuse, addiction, and fatal and non-fatal opioid overdose in patients with long-term use of opioid analgesics for management of chronic pain, including patients prescribed ER/LA OAs	05/05/2025 - 05/05/2025

Number of Committee Meetings Listed: 2

	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 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. Non-Federal members of this committee will serve as Special Government Employees, representatives or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. 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-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 January 10, 2025, the Anesthetic and Analgesic Drug Products Advisory Committee. discussed BLA 761393, condoliase injection submitted by Seikagaku Corp., for the proposed indication of the treatment of radicular leg pain associated with confirmed nerve root impingement caused by lumbar disc herniation in adults. The committee was tasked to discuss if the benefits of condoliase outweighed the risks. In general, a majority of the panelists (8 Yeses and 4 No's) voted that the Applicant had met substantial evidence of effectiveness. Agency Action: The Agency is reviewing recommendations made at the meeting. On May 5, 2025, 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. It is expected that the Committee will meet 3-5 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. They provide advice and input for FDA's consideration

as it makes regulatory decisions. 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

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 January 10, 2025, the Anesthetic and Analgesic Drug Products Advisory Committee. discussed BLA 761393, condoliase injection submitted by Seikagaku Corp., for the proposed indication of the treatment of radicular leg pain associated with confirmed nerve root impingement caused by lumbar disc herniation in adults. The committee was tasked to discuss if the benefits of condoliase outweighed the risks. In general, a majority of the panelists (8 Yeses and 4 No's) voted that the Applicant had met substantial evidence of effectiveness. Agency Action: The Agency is still reviewing recommendations made at the meeting. On May 5, 2025, the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee met jointly to discuss the findings of the completed

extended-release/long-acting opioid analgesic (ER/LA OA) postmarketing requirements (PMRs) 3033-1 and 3033-2 (https://www.fda.gov/media/95546/download). These PMRs are prospective (3033-1) and retrospective (3033-2) epidemiologic studies that examined the serious risks and predictors of misuse, abuse, addiction, and fatal and non-fatal opioid overdose in patients with long-term use of opioid analgesics for management of chronic pain, including patients prescribed ER/LA OAs. The Committees discussed their interpretation of the findings from PMRs 3033-1 and 3033-2 on the incidence and prevalence of misuse, abuse, Opioid Use Disorder (OUD), and fatal and nonfatal overdose in patients using OAs long-term, their thoughts on the most important findings, as well as any novel findings they believed FDA should communicate to healthcare providers, patients, and other members of the public. Agency Action: The Agency is still reviewing the recommendations made at the meeting.

Designated Federal Officer

Joyce Frimpong Designated Federal Officer

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; By courtesy, Professor of Epidemiology and Population Health, 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
Jowza, Maryam	04/01/2019	03/31/2027	Associate Professor of Anesthesiology and Pain Management, University of North Carolina-Chapel Hill	Special Government Employee (SGE) Member
Kennedy, D.J.	01/10/2025	01/10/2025	Professor, Physical Medicine & Rehabilitation Chair, Department of Physical Medicine & Rehabilitation Vanderbilt University Medical Center	Special Government Employee (SGE) Member
Kirkpatrick, John	01/10/2025	01/10/2025	Orthopedic Surgical Services, Orlando VA Medical Center	Regular Government Employee (RGE) Member
McAuliffe, Maura	03/29/2019	03/31/2026	Professor Emeritus, College of Nursing, Founding Director, Nurse Anesthesia Program 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
Nelson, Ariana	01/10/2025	01/10/2025	Associate Professor, Department of Anesthesiology and Perioperative Medicine University of California Irvine	Special Government Employee (SGE) Member

O'Brien, Joseph	01/10/2025	01/10/2025	National Scoliosis Foundation	Special Government Employee (SGE) Member
Reich, Jeffrey	12/23/2024	10/31/2027	CEO and Co-Founder, Sparian Biosciences	Representative Member
Richmond, Rebecca	04/01/2021	03/31/2025	Associate Chief Pharmacy Officer, Central Pharmacy Services, Duke University Hospital	Special Government Employee (SGE) Member
Schiff, Steven	01/10/2025	01/10/2025	Harvey and Kate Cushing Professor of Neurosurgery, Vice Chair for Global Health, Department of Neurosurgery, Yale University	Special Government Employee (SGE) Member
Sprintz, Michael	04/01/2019	03/31/2027	Clinical Assistant Professor, Division of Geriatric and Palliative Medicine, University of Texas Health Science Center	Special Government Employee (SGE) Member
Stojanovic, Milan	01/10/2025	01/10/2025	Assistant Professor of Anesthesiology Harvard Medical School	Regular Government Employee (RGE) Member

Number of Committee Members Listed: 14

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 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?
63

Number of Recommendations Comments
The Committee made 63 recommendations from FY-03 through FY-25.

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.

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