2024 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	2024

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
0	0	0	0	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 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-23, 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 February 15, 2023, a meeting was held jointly with the Nonprescription Drugs Advisory Committee. Further information regarding this meeting is provided in the Recommendation Remarks section. On April 19, 2023, the Anesthetic and Analgesic Drug Products Advisory Committee met to discuss postmarketing requirement (PMR) 3033-11, issued to application holders of new drug applications (NDAs) for extended-release and long-acting opioid analgesics to evaluate long-term efficacy of opioid analgesics and the risk of opioid-induced hyperalgesia. The discussion focused on a clinical

trial designed to address these objectives. Agency Action: The Agency is still reviewing the recommendations made at the meeting. It is expected that the Committee will meet 3-5 times during FY-24.

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-23.

21. Remarks
There were no reports required for this Committee in FY-23. In FY-23, 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 February 15, 2023, a meeting was held jointly with the Nonprescription Drugs Advisory Committee to discuss supplemental new drug application 208411/S–006, for NARCAN (naloxone hydrochloride) nasal spray, 4 mg/0.1 mL, submitted by Emergent BioSolutions Inc.

NARCAN is proposed for nonprescription treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. The issues for discussion was on the adequacy of the data supporting the nonprescription application. This product represented a potential first in class product in a new therapeutic category for nonprescription drugs. The members unanimously (19 to 0) agreed that the benefit profile of Narcan Nasal Spray was supportive of its use as a nonprescription opioid overdose reversal agent. Agency Action: On March 29, 2023, the Agency approved Narcan, 4 milligram (mg) naloxone hydrochloride nasal spray for over-the-counter (OTC), nonprescription, use – the first naloxone product approved for use without a prescription. Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose. Although the current charter states that the Committee shall hold meetings approximately 3-5 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. GSA Comment: The agency did not complete the FY23 ACR for this committee.

Designated Federal Officer

Moon Choi 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
Horrow, Jay	11/01/2019	10/31/2023	Clinical Lead, Cardiovascular Drug Development, Bristol-Myers Squibb	Representative Member
Jowza, Maryam	04/01/2019	03/31/2027	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 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
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

Richmond, Rebecca	04/01/2021	03/31/2025	Associate Chief Pharmacy Officer, Central Pharmacy Services, Duke University Hospital	Special Government Employee (SGE) Member
Shoben, Abigail	06/05/2015	03/31/2024	Associate Professor, Division of Biostatistics Ohio State 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
Zaafran, Sherif	04/01/2020	03/31/2024	President, Texas Medical Board	Special Government Employee (SGE) Member

Number of Committee Members Listed: 11

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?
61

Number of Recommendations Comments
The Committee made 61 recommendations from FY-03 through FY-23.

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