2025 Current Fiscal Year Report: Antimicrobial 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.
Antimicrobial Drugs Advisory Committee	109

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	10/07/2024	10/07/2026	

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
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. 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 for use in the treatment of infectious diseases and disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are authorities in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology, statistics, and related specialties. The committee includes one technically qualified voting member who is identified with consumer interests. 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-24, the Committee held one meeting. On September 9, 2024, the Committee met to discuss new drug application 213972, for oral sulopenem etzadroxil/probenecid tablets consisting of 500 milligrams (mg) sulopenem etzadroxil and 500 mg probenecid, submitted by Iterum Therapeutics US Ltd., for the proposed indication of treatment of uncomplicated urinary tract infections caused by designated susceptible bacteria in adult women 18 years of age and older. The Committee discussed the overall benefits and risks for the use of sulopenem etzadroxil/probenecid for the proposed indication. In addition, the Committee discussed the considerations that would be important for medical providers to know to ensure appropriate use of sulopenem etzadroxil/probenecid. Agency Action: The Agency is still reviewing the recommendations made at the meeting. It is expected that the Committee will meet 2-4 times during FY-25.

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 that FDA considers as part of its regulatory decision-making process. 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-24.

21. Remarks

There were no reports required for this Committee in FY-24. Although the current charter states that the Committee shall hold meetings approximately 2-4 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. Recruitment of Chairperson is being vetted by reviewing the participation of current members.

Designated Federal Officer

Yvette Waples Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Chandra, Richa	11/01/2019	10/31/2027	Clinical Development Head, Global Health Development, Novartis Pharmaceuticals	Representative Member

Clark, Nina	08/30/2024	11/30/2027	Professor of Medicine, Co-Director of Infectious Disease & Immunology Research Institute, Stritch School of Medicine, Loyola University, Division Director of Infectious Diseases, Director of Transplant Infectious Diseases Program,Loyola University Medical	Special Government Employee (SGE) Member
Green, Michael	05/31/2016	11/30/2025	Professor of Pediatrics, Surgery and Clinical & Translational Science, University of Pittsburgh School of Medicine; Director, Antimicrobial Stewardship & Infection Prevention; Co-Director, Transplant Infectious Diseases Children's Hospital of Pittsburgh	Special Government Employee (SGE) Member

Hardy, William	12/01/2019	11/30/2027	Scientific and Medical Consultant, Adjunct Clinical Professor of Medicine, Division of Infectious Diseases, Keck School of Medicine of University of Southern California	Special Government Employee (SGE) Member
Hunsberger, Sally	12/01/2020	11/30/2024	Biostatistician, Biometrics Research Branch, National Institute of Allergy and Infectious Diseases, National Institutes of Health	Regular Government Employee (RGE) Member
Patel, Nimish	11/16/2022	11/30/2025	Professor of Clinical Pharmacy, Skaggs School of Pharmacy and Pharmaceutical Sciences, University of California San Diego, Division of Clinical Pharmacy	Special Government Employee (SGE) Member
Perez, Federico	12/01/2020	11/30/2024	Infectious Disease Physician, Louis Stokes Cleveland VA Medical Center; Associate Professor of Medicine, Case Western Reserve University	Regular Government Employee (RGE) Member

Rose, Stacey	08/30/2024	11/30/2027	Associate Professor of Department of Medicine Section of Infectious Diseases and Huffington Department of Education, Innovation and Technology, Associate Professor of Center for Professionalism, Baylor College of Medicine	Special Government Employee (SGE) Member
Siberry, George	12/01/2018	11/30/2026	Senior Clinical Advisor to the Director, Office of HIV/AIDS, Bureau of Global Health United States Agency for International Development	Regular Government Employee (RGE) Member
Swaminathan, Sankar	12/01/2018	11/30/2026	Don Merrill Rees Presidential Endowed Chair; Professor and Chief, Division of Infectious Diseases, Department of Internal Medicine, University of Utah School of Medicine	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 Antimicrobial Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and make 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. The meeting minutes for the 09/09/2024 meeting are currently being reviewed and will be posted to the committee website as soon as they become available.

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 Antimicrobial Drugs 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 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?

67

Number of Recommendations Comments

The Committee made 67 recommendations from FY-03 through FY-24.

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