2024 Current Fiscal Year Report: Antimicrobial Drugs Advisory Committee

Report Run Date: 04/23/2024 11:12:59 AM

1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2024

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	10/07/2022	10/07/2024	

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 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-23, the Committee held four meetings. On January 24, 2023, the Committee discussed new drug application 217417, for rezafungin lyophilized powder for injection, submitted by Cidara Therapeutics, Inc., for treatment of candidemia and invasive candidiasis in adults. The issue that the Committee discussed included the overall benefit-risk assessment for the use of rezafungin for treatment of candidemia/invasive candidiasis in adult patients. There was one voting question, and a majority of the Committee (14 Yeses, 1 Noes) agreed that the overall benefit-risk assessment is favorable for the use of rezafungin for treatment of candidemia/invasive candidiasis in adults with limited or no alternative treatment options. Agency Action: On March 22, 2023, the Agency approved Rezzayo (rezafungin) for the treatment of candidemia and invasive candidiasis in patients 18 years of age or older who have limited or no alternative options. On March 16, 2023, the Committee discussed new drug application (NDA) 217188, for Paxlovid (nirmatrelvir and ritonavir co-packaged tablets) for oral use, submitted by Pfizer, Inc. The proposed indication is treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. The issues that the Committee discussed included the strength of evidence for use of Paxlovid for the treatment of

mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, and the strength of evidence for an association between use of Paxlovid in the treatment of mild-to-moderate COVID-19 and "COVID-19 rebound". There was a voting question, and a majority of the Committee (16 Yeses, 1 Noes) agreed that the overall benefit-risk assessment is favorable for Paxlovid when used for the treatment of mild-to-moderate COVID-19 in adults who are non-immune and at high risk for progression to severe COVID-19, including hospitalization or death. Agency Action: On May 25, 2023, the Agency approved the oral antiviral Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid is the fourth drug—and first oral antiviral pill—approved by the FDA to treat COVID-19 in adults. On April 17, 2023, the Committee discussed new drug application (NDA) 216974, for sulbactam-durlobactam for injection, submitted by Entasis Therapeutics, Inc. The Applicant’s proposed indication is treatment of hospitalacquired bacterial pneumonia (HABP) and ventilatorassociated bacterial pneumonia (VABP) caused by susceptible strains of Acinetobacter baumanniicalcoaceticus complex (ABC) in adults. The issue that the Committee discussed included the overall benefit-risk assessment for the use of sulfactam-durlobactam for the treatment of patients with HABP and VABP. There was one voting question, and the Committee unanimously (12 Yeses, 0 Noes) agreed that the overall benefitrisk assessment is favorable for the use of sulbactam-durlobactam for the treatment of patients 18 years or older with HABP and VABP

caused by susceptible strains of Acinetobacter baumanniicalcoaceticus complex (ABC) organisms. Agency Action: On May 23, 2023, the Agency approved Xacduro (sulbactam for injection; durlobactam for injection), a new treatment for hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) caused by susceptible strains of bacteria called Acinetobacter baumannii-calcoaceticus complex, for patients 18 years of age and older. On June 8, 2023, the Committee discussed biologics license application (BLA) 761328, for nirsevimab, a long-acting respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody for intramuscular use, submitted by AstraZeneca AB. The proposed indication is prevention of RSV lower respiratory tract disease in: Neonates and infants born during or entering their first RSV season. Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. The issues that the Committee discussed included benefits and risks for nirsevimab when assessed by chronological and gestational age group in relationship to the population or subpopulation for whom nirsevimab administration in the first RSV season would be most appropriate, and additional data may be helpful to inform future recommendations regarding the use of nirsevimab in infants born to mothers who received RSV vaccination in the contest of potential, future availability of maternal RSV vaccine to protect infants from RSV disease during their first RSV season. There were two voting questions. For the first voting question, the Committee unanimously (21 Yeses, 0 Noes) agreed that the overall benefit-risk assessment is favorable for the use of nirsevimab for the proposed indication of the prevention of RSV

lower respiratory tract disease in neonates and infants born during or entering their first RSV season. For the second voting question, a majority of Committee (19 Yeses, 2 Noes) agreed that the overall benefit-risk assessment is favorable for the use of nirsevimab for the proposed indication of the prevention of RSV lower respiratory tract disease in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. Agency Action: On July 17, 2023, the Agency approved Beyfortus (nirsevimab-alip) for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season, and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. It is expected that the Committee will meet two to four 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.

Designated Federal Officer

She-Chia C. Jankowski Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Baden, Lindsey	06/11/2018	11/30/2023	Director of Clinical Research, Division of Infectious Diseases, Brigham and Women's Hospital; Director, Infectious Disease Service, Dana-Farber Cancer Institute; Professor of Medicine, Harvard Medical School	Special Government Employee (SGE) Member
Chandra, Richa	11/01/2019	10/31/2023	Clinical Development Head, Communicable Diseases, Global Health Development Unit, Novartis Pharmaceuticals	Representative 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	11/30/2023	Attending, Rand Schrader (HIV) Clinic	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

Murphy, Richard	12/01/2019	11/30/2023	Chief, Infectious Diseases, VA White River Junction Medical Center Medicine Service	Regular Government Employee (RGE) Member
Ofotokun, Ighovwerha	12/27/2016	11/30/2024	Professor of Medicine, Division of Infectious Diseases, Emory University School of Medicine; Infectious Disease Specialist, Grady Memorial Health System	Special Government Employee (SGE) 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
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
Walker, Roblena	04/03/2019	11/30/2023	CONSUMER REPRESENTATIVE - Chief Executive Officer, EMAGAHA, INC.	Special Government Employee (SGE) Member

Number of Committee Members Listed: 12

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 Anti-Infective 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.

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?

66

Number of Recommendations Comments

The Committee made 66 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.

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