2024 Current Fiscal Year Report: Cardiovascular and Renal Drugs 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.
Cardiovascular and Renal Drugs Advisory Committee	817

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	08/27/2022	08/27/2024	

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 cardiovascular and renal disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

The Committee is balanced with respect to various aspects of cardiology. Committee members have

expertise in cardiology, hypertension, arrhythmia, angina, congestive heart failure, diuresis, and biostatistics. In addition the Committee has one consumer member and may include one non-voting member representing Industry.

20c. How frequent and relevant are the Committee Meetings?

In FY-23, the Committee met four times. On October 26, 2022, the Cardiovascular and Renal Drugs Advisory Committee discussed new drug application (NDA) 216951, for the hypoxia inducible factor prolyl hydroxylase inhibitor, daprodustat tablets, submitted by GlaxoSmithKline, LLC, for the treatment of anemia due to chronic kidney disease in adult patients not on dialysis and on dialysis. The majority of members (11 Noes and 5 Yeses) voted "No" indicating that the benefits of daprodustat do not outweigh its risks for the treatment of anemia due to CKD in adults not on dialysis. Agency Action: The Agency is still reviewing the recommendations made at the meeting. On November 16, 2022, the Cardiovascular and Renal Drugs Advisory Committee discussed new drug application 213931, for tenapanor hydrochloride tablets, submitted by Ardelyx, Inc., for the control of serum phosphorus levels in adults with chronic kidney disease on dialysis. The committee was asked to comment on whether the size of the treatment effect on serum phosphorus is clinically meaningful and whether tenapanor’s benefits outweigh its risks. The majority of the committee members (9 Yeses, 4 Noes, 0 Abstentions) voted “Yes,” agreeing that tenapanor’s benefits outweigh its risks for the control of serum phosphorus in adults with CKD on dialysis when administered as monotherapy. The majority of the committee members (10

Yeses, 2 Noes, 1 Abstention) voted “Yes”, indicating that tenapanor’s benefits outweigh its risks for the control of serum phosphorus in adults with CKD on dialysis when administered in combination with phosphate binder treatment. Agency Action: The Agency is still reviewing the recommendations made at the meeting. On December 13, 2022, the Cardiovascular and Renal Drugs Advisory Committee discussed new drug application (NDA) 216401, for omecamtiv mecarbil tablets, submitted by Cytokinetics, Inc. The proposed indication is to reduce the risk of cardiovascular death and heart failure events in patients with symptomatic chronic heart failure with reduced ejection fraction. The committee discussed whether the phase 3 trial (GALACTIC-HF) establishes substantial evidence of effectiveness of omecamtiv mecarbil and whether the benefits of omecamtiv mecarbil outweigh the risks when used according to the Applicant’s proposed dosing regimen. The majority of the Committee members (3 Yeses, 8 Noes) voted "No," indicating that the benefits of omecamtiv mecarbil do not outweigh its risks for the treatment of heart failure with reduced ejection fraction. Agency Action: The Agency is still reviewing the recommendations made at the meeting. On September 13, 2023, the Cardiovascular and Renal Drugs Advisory Committee discussed supplemental new drug application (sNDA) 210922-s015, for ONPATTRO (patisiran) lipid complex for injection, submitted by Alnylam Pharmaceuticals, Inc., for the proposed treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults. The Committee was asked to comment if patisiran's benefits outweigh its risks for the treatment of ATTR cardiomyopathy. The majority of the committee members (9 Yeses, 3 Noes, 0

Abstentions) voted “Yes,” agreeing that patisiran benefits outweigh its risk. Agency Action: The Agency is still reviewing the recommendations made at the meeting. It is expected that the Committee will meet one to three 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. GSA Comment: The agency did not complete the FY23 ACR for this committee.

Designated Federal Officer
Yvette Waples Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Bairey Merz, Cathleen Noel	07/01/2020	06/30/2024	Director, Barbra Streisand Women’s Heart Center, Cedars-Sinai Medical Center	Special Government Employee (SGE) Member
Butler, Javed	07/23/2020	06/30/2028	Distinguished Professor of Medicine, University of Mississippi	Special Government Employee (SGE) Member

Cook, Thomas	07/01/2020	06/30/2024	Professor (Clinical Health Sciences), Clinical Trials Program, Department of Biostatistics and Medical Informatics, University of Wisconsin-Madison	Special Government Employee (SGE) Member
Kasper, Edward	07/01/2020	06/30/2024	Director of Outpatient Cardiology, E. Cowles Andrus Professor in Cardiology, Johns Hopkins School of Medicine	Special Government Employee (SGE) Member
Kovesdy, Csaba	07/01/2021	06/30/2025	Center Nephrology Section Chief, Memphis Veterans Affairs Medical Center	Regular Government Employee (RGE) Member
Moliterno, David	02/27/2019	06/30/2024	Professor of Internal Medicine, Division of Cardiovascular Medicine, University of Kentucky Medical Center	Special Government Employee (SGE) Member
O'Connor, Christopher	07/01/2021	06/30/2025	President and Executive Director, Inova Heart and Vascular Institute	Special Government Employee (SGE) Member
Peterson, Eric	08/18/2023	06/30/2027	Vice Provost. Senior Associate Dean, University of Texas Southwestern Medical Center	Special Government Employee (SGE) Member
Rossert, Jerome	03/24/2021	10/31/2023	Vice President, Head of Clinical Renal, Astra Zeneca	Representative Member
Roy-Chaudhury, Prabir	08/18/2023	06/30/2027	Drs. Ronald and Katherine Falk Eminent Professor and Co-Director University of North Carolina Kidney Center	Regular Government Employee (RGE) Member
Thadhani, Ravi	07/01/2020	06/30/2024	Executive Vice President for Health Affairs, Emory University	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 Cardiovascular and Renal 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 cardiovascular and renal diseases and making appropriate recommendations to the Commissioner of the Food and Drug Administration. 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 Cardiovascular and Renal 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?
64

Number of Recommendations Comments
The Committee has made 64 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 the 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
It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters 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
Recommendation: 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