2025 Current Fiscal Year Report: Pulmonary-Allergy 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.
Pulmonary-Allergy Drugs Advisory Committee	1011

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	05/30/2024	05/30/2026	

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 pulmonary disease and diseases with allergic and/or immunologic mechanisms 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 pulmonary medicine, allergy, clinical immunology, and epidemiology or statistics. The Committee includes one technically qualified member who is identified with consumer interests. The Committee may include one non-voting member identified with industry interests.

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

In FY-24, the Committee held 1 meeting. On November 17, 2023, the committee met to discuss new drug application 215010, for gefapixant oral tablets, submitted by Merck Sharp & Dohme Corp., for the proposed indication of treatment of adults with refractory or unexplained chronic cough. The majority of Committee members (1 Yeses and 12 Noes) voted that the evidence does not demonstrate that gefapixant provides a clinically meaningful benefit to adult patients with refractory or unexplained chronic cough, given the small reduction in cough frequency and results from PROs. It is expected that the Committee will meet 1-3 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. Their advice is considered by FDA as part of its regulatory decision-making. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientists on a

full-time basis at maximum rates 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.

Designated Federal Officer

Takyiah Stevenson Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Au, David	04/25/2017	05/31/2025	Center for Care and Payment Innovation, Office of Healthcare Innovation and Learning, Department of Veterans Affairs (VA), Professor of Medicine, University of Washington, Acting Executive Director	Regular Government Employee (RGE) Member
Bacharier, Leonard	06/15/2022	05/31/2026	Professor of Pediatrics, Section Chief, Pediatric Allergy and Immunology, Monroe Carell Jr. Children's Hospital, Vanderbilt University Medical Center	Special Government Employee (SGE) Member
D'Agostino, Emma	06/15/2022	05/31/2026	CONSUMER REPRESENTATIVE; Consultant, Cystic Fibrosis Foundation; Associate Medical Director, Virgo Health	Special Government Employee (SGE) Member
Evans, Scott	06/03/2019	05/31/2025	Professor and Chair ad interim, Department of Pulmonary Medicine, University of Texas MD Anderson Cancer Center	Special Government Employee (SGE) Member

Garibaldi, Brian	06/15/2022	05/31/2026	Professor of Medicine and Physiology, Division of Pulmonary and Critical Care Medicine, Johns Hopkins University School of Medicine	Special Government Employee (SGE) Member
Hamblett, Nicole	09/04/2023	05/31/2027	Professor, Department of Pediatrics, Adjunct Professor, Department of Biostatistics, University of Washington, Co-Executive Director, Development Network Coordinating Center, Seattle Children's Research Institute	Special Government Employee (SGE) Member
Kim, Edwin	10/03/2019	05/31/2027	Associate Professor and Division Chief, Division of Pediatric Allergy and Immunology, University of North Carolina School of Medicine	Special Government Employee (SGE) Member
Krop, Julie	02/14/2024	10/31/2027	Chief Medical Officer and Head of Development, Translational Science; Clinical Development, PureTech Health	Representative Member
Lee, Janet	06/15/2022	05/31/2026	Professor of Medicine; Chief, Division of Pulmonary and Critical Care Medicine, Washington University in St. Louis	Special Government Employee (SGE) Member
Rank, Matthew	09/04/2023	05/31/2027	Professor of Medicine, Mayo Clinic Alix School of Medicine, Chair, Division of Allergy, Asthma, and Clinical Immunology, Mayo Clinic in Arizona	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 Pulmonary-Allergy Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of marketed and investgational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms and makes recommendations to the Commissioner of Food and Drugs. This advice is considered by FDA as part of its decision-making on 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
NA

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 Pulmonary-Allergy Drugs Advisory Committee enabled 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?
36

Number of Recommendations Comments
The Committee made 36 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 or other regulatory decision-making.

Is the Committee engaged in the review of applications for grants?
No

Grant Review Comments

NA

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

NA