2024 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	2024

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	05/30/2022	05/30/2024	

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 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 are experts in the fields of pulmonary

medicine, allergy, clinical immunology, and epidemiology/statistics and are qualified by training and experience to evaluate scientific data. 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-23, the Committee held 3 meetings. On November 8, 2022, the Pulmonary-Allergy Drugs Advisory Committee discussed the new drug application 214070, for a fixed dose combination of budesonide and albuterol sulfate metered dose inhaler, submitted by AstraZeneca and Bond Avillion 2 Development LP. The proposed indication is as-needed treatment or prevention of bronchoconstriction and for the prevention of exacerbations in patients with asthma 4 years of age and older. A majority of the committee members (16 Yeses and 1 No) voted that the data supports a favorable benefit risk assessment for use of budesonide and albuterol sulfate metered dose inhaler (BDA) in patients 18 years of age with asthma. A slight majority of the committee members (8 Yeses and 9 Noes) voted that the data do not support a favorable benefit risk assessment for use of BDA in patients 12 to <18 years of age with asthma. A majority of the committee members (1 Yes and 16 Noes) voted that the data does not support a favorable benefit risk assessment for use of BDA in patients 4 to <12 years of age with asthma. Agency Action: On January 11, 2023, the Agency approved albuterol and budesonide (Airsupra, AstraZeneca Pharmaceuticals LP) inhalation aerosol for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of

asthma attacks in patients with asthma 18 years of age and older. On November 9, 2022, the Pulmonary-Allergy Drugs Advisory Committee discussed the request for Emergency Use Authorization 113, for sabizabulin oral capsule, a tubulin polymerization inhibitor, submitted by Veru Inc., for the treatment of SARS-CoV-2 infection in hospitalized patients with moderate to severe COVID-19 infection who are at high risk of acute respiratory distress syndrome. A focus of the discussion included the treatment effect size in the context of the high placebo mortality rate, the limited size of the safety database, and identifying the proposed population. A majority of the committee members (5 Yeses and 8 Noes) voted that the known and potential benefits of VERU-111 when used for the treatment of adult patients hospitalized with COVID-19 at high risk of ARDS do not outweigh the known and potential risks of VERU-111. Agency Action: The Agency is reviewing recommendations made at the meeting. On May 11, 2023, the Pulmonary-Allergy Drugs Advisory Committee discussed new drug application (NDA) 214697, for epinephrine nasal spray, submitted by ARS Pharmaceuticals Inc., for the proposed indication of emergency treatment of allergic reactions (Type I) including anaphylaxis in adults and children 30 kilograms. A majority of the committee members (16 Yeses and 6 Noes) voted that the pharmacokinetic/pharmacodynamic (PK/PD) results support a favorable benefit-risk assessment for ARS-1 in adults for the emergency treatment of allergic reactions (Type I) and anaphylaxis. A majority of the committee members (17 Yeses and 5 Noes) voted that the PK/PD results support a favorable benefit-risk assessment for ARS-1 in children (<18 years of age) 30 kg for the emergency treatment of allergic reactions (Type I) and anaphylaxis. Agency

Action: The Agency is reviewing 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 lends credibility to FDA's regulatory decisions. 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-23.

21. Remarks
There were no reports required for this Committee in FY-23.

Designated Federal Officer
Takyiah Stevenson Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Au, David	04/25/2017	05/31/2025	Director, Center of Innovation for Veteran-Centered and Value-Driven Care, VA Puget Sound Health Care System, Seattle Division; Professor of Medicine, University of Washington	Regular Government Employee (RGE) Member
Bacharier, Leonard	06/15/2022	05/31/2026	Section Chief, Pediatric Allergy and Immunology, Vanderbilt University Medical Center	Special Government Employee (SGE) Member

Carlson, Dawn	11/01/2019	10/31/2023	Vice President, Neuroscience Development, Abbvie, Inc	Representative 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
Garibaldi, Brian	06/15/2022	05/31/2026	Associate Professor of Medicine and Physiology, Johns Hopkins University School of Medicine	Special Government Employee (SGE) Member
Hamblett, Nicole	09/04/2023	05/31/2027	Professor, University of Washington; Co-Executive Director, Seattle Children's Research Institute	Special Government Employee (SGE) Member
Holguin, Fernando	10/06/2021	05/31/2025	Director of the Asthma Program at the Center for Lungs and Breathing, University of Colorado	Special Government Employee (SGE) 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 in Arizona	Special Government Employee (SGE) Member

Number of Committee Members Listed: 9

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 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

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?
35

Number of Recommendations Comments
The Committee made 35 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 product.

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