2025 Current Fiscal Year Report: Blood Products 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.
Blood Products Advisory Committee	224

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	05/13/2024	05/13/2026	

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 data on the safety and effectiveness of blood products intended for use in the diagnosis, prevention or treatment of human diseases. On May 9, 2024, the committee met by web conference in open session to discuss strategies to reduce the risk of transfusion-transmitted malaria by testing blood donations from donors at risk of malaria exposure. FDA intends to issue a guidance document with

recommendations for blood establishments with revised recommendations to reduce the risk of transfusion-transmitted malaria.

20b. How does the Committee balance its membership?

The committee consists of experts in clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biotechnology, and other related specialties. One member is technically qualified and identified with consumer interests and one non-voting member represents the point of view of industry.

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

The committee held one advisory committee meeting on May 9, 2024, in FY2024. One advisory committee meeting and one intramural laboratory research site visit are planned for FY 2025.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the committee are drawn from academia, research, clinical practice, and consumer interests. Their advice and input assists FDA in making its 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?

This committee held no closed meetings in FY 2024.

21. Remarks

No reports are required from this committee.

Designated Federal Officer

Christina Marie Vert Center for Biologics Evaluation and Research, FDA

Committee Members	Start	End	Occupation	Member Designation
Ahuja, Sanjay	10/01/2023	09/30/2027	Professor, Case Western Reserve University and Director, Rainbow Hemostasis and Thrombosis Center, Rainbow Babies and Children's Hospital Cleveland, OH	Special Government Employee (SGE) Member
Ballow, Mark	01/27/2020	09/30/2027	Professor, University of South Florida	Special Government Employee (SGE) Member
Basavaraju, Sridhar	06/28/2021	09/30/2025	Director, Office of Blood, Organ, & Other Tissue Safety, Centers for Disease Control & Prevention, Atlanta GA	Regular Government Employee (RGE) Member
Bloch, Evan	02/15/2019	09/30/2027	Assistant Professor/Associate Director, Transfusion Medicine, Johns Hopkins University School of Medicine	Special Government Employee (SGE) Member
Cumming, Melissa	10/01/2021	09/30/2025	Epidemiologist III, Bureau of Infectious Disease and Laboratory Sciences, Massachusetts Department of Health	Special Government Employee (SGE) Member
Lattimore, Susan	10/01/2021	09/30/2025	Consumer Representative, Associate Director, The Hemophilia Center, Institute on Development and Disability, Oregon Health and Science University	Special Government Employee (SGE) Member

Maldarelli, Frank	10/01/2022	09/30/2026	Senior Investigator, Head, Clinical Retrovirology Section, National Cancer Institute, National Institutes of Health, Fort Detrick, MD	Regular Government Employee (RGE) Member
Mondoro, Traci	10/01/2023	09/30/2027	Associate Director, Division of Blood Diseases and Resources, Chief, Translational Blood Sciences and Resources Branch, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD	Regular Government Employee (RGE) Member
Pandey, Suchitra	10/01/2023	09/30/2027	Industry Representative, Chief Medical Officer, Stanford Blood Center, Palo Alto, CA	Representative Member
Perez, Elena	07/22/2019	09/30/2027	Associate of Allergy Associates of the Palm Beaches, Pediatric Allergy/Immunology	Special Government Employee (SGE) Member
Perkins, Jeremy	10/01/2020	09/30/2028	Deputy Director, Murtha Cancer Center, Walter Reed National Military Medical Center, Bethesda, MD	Regular Government Employee (RGE) Member
Scanlan, Richard	10/01/2022	09/30/2026	Vice Chair of Laboratory Medicine Transfusion Service, Medical Director, Oregon Health and Science University, Portland, OR	Special Government Employee (SGE) Member
Sherman, Kenneth	10/01/2022	09/30/2026	Professor, Division Chief Division of Digestive Diseases, University of Cincinnati College of Medicine, Cincinnati, OH	Special Government Employee (SGE) Member

Szczepiorkowski, Zbigniew	10/18/2022	09/30/2026	Professor of Pathology and Laboratory Medicine, Dartmouth's Geisel School of Medicine, Medical Director, Transfusion Medicine Service, Dartmouth-Hitchcock Medical Center, Lebanon, NH	Special Government Employee (SGE) Member
Wahed, Abdus	10/01/2021	09/30/2025	Professor of Biostatistics, University of Rochester, Rochester, NY	Special Government Employee (SGE) Member

Number of Committee Members Listed: 15

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 Blood Product Advisory Committee supports FDA's mission and strategic action plan by reviewing and evaluating data on the safety and effectiveness of blood products intended for use in the diagnosis, prevention or treatment of human diseases. The Committee also considers the quality and relevance of FDA's research program which, provides scientific support for the regulation of these products. The Committee supports FDA's mission by using science-based risk management in all of its activities. The Committee recommendations provide the most health promotion and protection at the least cost for the public. This Committee assists the Agency by providing external input if needed for timely, high quality, cost-effective processes for review of new technologies/pre-market submissions, effective communication and working relationships with stakeholders to enhance U.S. and global

health outcomes, accurately analyzing risks associated with medical products, facilitating the development and availability of medical countermeasures to limit the effects of a terrorist attack on the civilian and military populations, protecting the safety and security of biologics (vaccines, blood, and blood products), all key components of FDA's strategic plan objectives.

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 Blood Products 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?
120

Number of Recommendations Comments
The Committee made 120 recommendations from FY2003 through FY2024.

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, and 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 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 an investigational new medical product or take other regulatory action.

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

N/A