2024 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	2024

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	05/13/2022	05/13/2024	

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 data on the safety and effectiveness of blood products intended for use in the diagnosis, prevention or treatment of human diseases. On December 8, 2022, the committee met by web conference to hear an overview of the research programs of the Laboratory of Emerging Pathogens and the Laboratory of Molecular Virology, Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review, Center for Biologics Research. After the open session, the meeting was closed to the public to make recommendations to the Agency on specific research programs. The recommendations of the committee were utilized by FDA as part of its

independent intramural program review of research priorities. On April 26, 2023, the committee met by web conference to hear an overview of the research programs in the Division of Hemostasis, Office of Plasma Protein Therapeutics Chemistry, Manufacturing, and Controls, Office of Therapeutic Products, Center for Biologics Evaluation and Research. After the open session, the meeting was closed to the public to make recommendations to the Agency on specific research programs. The recommendations of the committee were utilized by FDA as part of its independent intramural program review of research priorities.

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 two advisory committee meetings on December 8, 2022, and April 26, 2023, and conducted one intramural laboratory research site visit on November 3, 2022, in FY 2023. One advisory committee meeting is planned for FY 2024.

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 lends

credibility to regulatory decisions made and has representatives of knowledge and experience needed from informed sources. 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 compensations.

20e. Why is it necessary to close and/or partially closed committee meetings?

This committee held two closed meetings for this fiscal year. The two meetings were both closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the individual investigators' research programs, along with other information, were discussed during the closed sessions. The public discussion of these recommendations about individual scientists would constitute an unwarranted invasion of personal privacy.

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
Adimora, Adaora	10/01/2021	09/30/2025	Professor, University of North Carolina at Chapel Hill	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
Grossman, Brenda	10/01/2020	09/30/2024	Medical Director, Barnes-Jewish Hospital, St. Louis, MO	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
Marques, Marissa	10/01/2020	09/30/2024	Professor, University of Alabama, Birmingham, AL	Special Government Employee (SGE) 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	09/30/2024	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 tabacco 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 in ensuring 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?

119

Number of Recommendations Comments

The Committee made 119 recommendations from FY2003 through FY2023.

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
The Agency 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
FDA approves or chooses not to approve an investigational 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

N/A