2026 Current Fiscal Year Report: Vaccines and Related Biological Products Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2026

3. Committee or Subcommittee	3b. GSA Committee No.
Vaccines and Related Biological Products Advisory Committee	1041

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	12/31/2025	12/31/2027	

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	12/31/1979	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 Vaccines and Related Biological Products Advisory Committee (VRBPAC) reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines, allergenics, and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and as required, any other products for which the Food and Drug Administration has regulatory responsibility. The

Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in immunology, allergy and allergenic diseases, molecular biology, rDNA, virology; bacteriology, parasitology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, hypersensitivity reactions to vaccines, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry. There also may be one member that is technically qualified and identified with consumer interests and one non-voting member that represents the point of view of industry.

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

The committee held 3 meetings in FY25 and estimates that this committee will hold 6 meetings in FY26. The Committee receives information regarding the scope and mission of the research programs from the Office of Vaccines Research and Review (OVRR). All discussions are related to components of the Strategic Plan and FDA's Critical Path to New Medical Products. 1. October 10, 2024 – VRBPAC Meeting Topic I: The committee discussed and made recommendations on the strain selection for the influenza virus vaccines for the 2025 Southern Hemisphere influenza season. Committee Recommendation: VRBPAC concurred with the World Health

Organization (WHO) recommendations and advised inclusion of the following strains in the 2025 Southern Hemisphere influenza vaccine formulation: • A/Victoria/4897/2022 (H1N1)pdm09-like virus • A/Thailand/8/2022 (H3N2)-like virus • B/Austria/1359417/2021-like virus (B/Victoria lineage) • B/Phuket/3073/2013-like virus (B/Yamagata lineage) FDA Action/Outcome: The FDA adopted these recommendations and, on October 25, 2024, issued the official guidance titled "Recommended Composition of Influenza Virus Vaccines for Use in the 2025 Southern Hemisphere Influenza Season." This ensured U.S. vaccine composition aligned with WHO guidance and supported timely manufacturing for the Southern Hemisphere distribution period. Topic II: The committee discussed pandemic preparedness for highly pathogenic avian influenza virus, including considerations for vaccine composition for (H5) vaccines. Committee Recommendation: Members emphasized the need for continued surveillance of emerging H5 strains and the maintenance of candidate vaccine virus seed stocks. The committee supported CBER's ongoing evaluation of prototype H5 vaccines for potential use in pandemic preparedness. FDA Action/Outcome: FDA concurred with the committee's recommendations and noted that CBER would continue to coordinate with WHO and BARDA to update pandemic influenza reference strains and support evaluation of new H5 vaccine candidates under existing pandemic preparedness frameworks. Topic III: The committee heard an overview of the research programs in the Laboratory of Pediatric & Respiratory Viral Diseases (LPRVD) and the Laboratory of DNA Viruses (LDNAV) in the Division of Viral Products (DVP), Office of

Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER). A portion of the Meeting was held in closed session. Committee Recommendation: This session was informational only; no formal recommendations were made. FDA Action/Outcome: FDA acknowledged the committee's feedback and noted the presentations would inform CBER's ongoing regulatory science and research priorities. 2. December 12, 2024 – VRBPAC Meeting Topic I: The committee met in open session to discuss Considerations for Respiratory Syncytial Virus (RSV) Vaccine Safety in Pediatric Populations. Committee Recommendation: Members reviewed post-marketing safety data for the licensed adult RSV vaccines and emerging data from pediatric trials. The committee emphasized that additional long-term safety monitoring and rare adverse event surveillance are critical prior to extending vaccine indications to pediatric populations. No formal vote was taken. FDA Action/Outcome: FDA considered the committee's feedback in its ongoing regulatory evaluation of pediatric RSV vaccine development. CBER communicated with sponsors regarding the need for extended follow-up and enhanced pediatric safety monitoring consistent with the committee's discussion. Topic II: The committee met in open session to hear overviews of the Laboratory of Immunoregulation (LI) and Laboratory of Retroviruses (LR) research programs in the Division of Viral Products (DVP), OVRR, CBER. After the open session ended for Topic II, the meeting was closed to the public for committee deliberations. Committee Recommendation: This was an informational research review; no recommendations were required. FDA Action/Outcome: FDA acknowledged the committee's input and noted that the presentations

will guide future CBER research planning and oversight. 3. May 22, 2025 – VRBPAC Meeting The committee met in open session to discuss and make recommendations on the selection of the 2025 – 2026 formula for COVID-19 vaccines for use in the United States. Committee Recommendation: VRBPAC unanimously recommended that the 2025 – 2026 COVID-19 vaccine composition be updated to target the SARS-CoV-2 JN.1 lineage, determining this strain most closely represents current circulation and would provide optimal protection for the upcoming season. FDA Action/Outcome: On May 31, 2025, FDA announced it had accepted the committee's recommendation and directed manufacturers to update their vaccine formulations accordingly. CBER issued updated guidance letters to industry and coordinated with CDC on the implementation of the 2025 – 2026 COVID-19 vaccination program. The decision was reflected in FDA's public communications and industry guidance materials released in June 2025.

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. They provide advice and input that FDA considers as part of its regulatory decision-making process. 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?
There were two closed session meetings held in FY 2025 (10/10/2024, Topic III, and 12/12/2024, Topic III). These portions of the aforementioned

meetings were closed in accordance with 21 CFR section 14.27(b), implementing 5 USC 552b(c)(6), for the review of matters that would constitute a clearly unwarranted invasion of personal privacy if disclosed.

21. Remarks

Designated Federal Officer

Cicely Reese Designated Federal Officer, DSAC, Center for Biologics Evaluation and Research, FDA

Committee Members	Start	End	Occupation	Member Designation
Berger, Adam	02/01/2022	01/31/2026	National Instituters of Health	Regular Government Employee (RGE) Member
Bernstein, Henry	02/01/2022	01/31/2026	Cohen Children's Medical Center	Special Government Employee (SGE) Member
Chatterjee, Archana	06/21/2019	01/31/2027	Chair and Dean, Department of Pediatrics, University of South Dakota	Special Government Employee (SGE) Member
Durbin, Anna	02/01/2025	01/31/2029	Professor, Department of International Health Director, Center for Immunization Research Johns Hopkins Bloomberg School of Public Health	Special Government Employee (SGE) Member
El Sahly, Hana	06/10/2016	01/31/2026	Professor/Baylor College Of Medicine	Special Government Employee (SGE) Member
Gans, Hayley	06/21/2019	01/31/2027	Professor, Department of Pediatrics, Stanford University Medical Center	Special Government Employee (SGE) Member
Jodar, Luis	02/01/2024	01/31/2028	Chief Medical Officer, Senior Vice President, Pfizer	Representative Member

Meyer, Sarah	02/01/2024	01/31/2028	Immunization Services Division National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention	Regular Government Employee (RGE) Member
Monto, Arnold	02/01/2022	01/31/2026	Professor/University of Michigan	Special Government Employee (SGE) Member
Munoz-Rivas, Flor	02/01/2025	01/31/2029	Associate Professor of Pediatrics, Infectious Diseases Molecular Virology and Microbiology Texas Children's Hospital Baylor College of Medicine	Special Government Employee (SGE) Member
Nelson, Michael	07/05/2024	01/31/2028	Chief Asthma, Allergy and Immunology Division School of Medicine University of Virginia	Special Government Employee (SGE) Member
Omer, Saad	02/01/2025	01/31/2029	Dean and Professor Lyda Hill Deanship of the School of Public Health UT Southwestern Medical Center	Special Government Employee (SGE) Member
Perlman, Stanley	08/23/2022	01/31/2026	Physician - University of Iowa	Special Government Employee (SGE) Member
Rubin, Eric	02/01/2022	01/31/2026	Adjunct Professor, Harvard, TH Chan school of Public Health	Special Government Employee (SGE) Member

Number of Committee Members Listed: 14

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 Vaccines and Related Biological Products Advisory Committee supports FDA's mission and strategic action plan by reviewing and evaluating available data relating to the safety and effectiveness of vaccines and related biological products, which are intended for, use in the prevention, treatment, or diagnosis of human diseases. The Committee also considers the quality and relevance of FDA's research programs which provides scientific support for the regulation of these products. The Committee supports FDA's mission by using science-based efficient 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, especially vaccines, 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 Vaccines and Related Biological 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?
149

Number of Recommendations Comments
The Committee made approximately 149 recommendations from FY2003 through FY2025.

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.

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 a new medical product 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

N/A