2024 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	2024

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	12/31/2021	12/31/2023	

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. 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 Vaccines and Related Biological Products Advisory Committee (VRBPAC) reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines 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, molecular biology, rDNA, virology; bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry. 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 6 meetings in FY23 and estimate that this committee will hold 12 meetings in FY24. 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 5, 2022 – The committee met in open session via web conference to discuss the Strain Selection for the Influenza Virus Vaccines for the 2023 southern hemisphere Influenza Season. Agency Action: On February 13, 2023, FDA approved Fluzone Quadrivalent, southern hemisphere and Fluzone Quadrivalent High-Dose southern hemisphere for the 2023 southern hemisphere influenza season. 2. January 26, 2023 – The committee met in open session via web conference to discuss future vaccination regimens addressing COVID-19. Agency Action: A. In March 2023, FDA notified COVID-19 vaccine manufacturers that they should plan to implement the proposals discussed at the

January 26, 2023, VRBPAC and supported by the committee's vote and discussion. Specifically, FDA noted that the process of moving to a single vaccine strain composition, i.e., Original and Omicron BA.4/BA.5 for all mRNA-based COVID-19 vaccines, should also involve the consolidation of the different age group fact sheets for healthcare providers and for recipients and caregivers into a single fact sheet for healthcare providers and a single fact sheet for recipients and caregivers for each vaccine, and to simplify the vaccination regimens to the extent appropriate. Given the current state of naturally acquired, vaccine-induced, and hybrid (combined natural infection in the setting of at least one COVID-19 vaccination) immunity in the US population, FDA suggested for each of the authorized bivalent vaccines to move to a single dose for most individuals, with additional doses for the very young, those 65 years and older, and individuals with certain kinds of immunocompromise. B. On April 18, 2023, the FDA authorized the use of the bivalent COVID-19 vaccines in all individuals 6 months of age and older allowing for use of a single dose in most adults and pediatric populations; two or three doses (based on the vaccine used) in the youngest pediatric populations, an additional dose for persons 65 years of age and older, and additional age-appropriate doses for persons with certain kinds of immunocompromise. The EUA actions on April 18, 2023, resulted in FDA no longer authorizing use of monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines (containing the mRNA encoding spike protein of Original SARS-CoV-2 virus) and certain uses of the approved COVID-19 vaccines in the United States. C. In the April 28, 2023, revision to the Pfizer BioNTech COVID-19 Vaccine EUA, FDA

authorized the following uses of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals 6 months through 4 years of age with certain kinds of immunocompromise who have previously received three doses of Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent: i. A fourth dose administered at least 1 month following the most recent dose. ii. additional doses that may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. 3. February 28- Topic I: The committee met in open session via web conference to discuss and make recommendations on the safety and effectiveness of ABRYSVO (Respiratory Syncytial Virus Vaccine), manufactured by Pfizer Inc., with a requested indication, in Biologics License Application # 125769 (STN 125769/0), for active immunization for the prevention of acute respiratory disease and lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 60 years of age and older Agency Action (Topic I): On May 31, 2023, FDA approved ABRYSVO for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. March 1, 2023- Topic II: The committee met in open session via web conference to discuss and make recommendations on the safety and effectiveness of AREXVY (Respiratory Syncytial Virus Vaccine, Recombinant, Adjuvanted), manufactured by GSK, with a requested indication, in Biologics License Application # 125775 (STN 125775/0), for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus RSV-A and RSV-B subtypes in adults 60

years of age and older. Agency Action (Topic II): On May 3, 2023, FDA approved AREXVY for active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older. 4. March 7, 2023 - The committee met in open session via web conference to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2023 – 2024 northern hemisphere influenza season. Agency Action: On June 30, 2023, FDA approved 2023-2024 Unites States Formulation of Influenza vaccines for the 2023-2024 northern hemisphere influenza season. 5. May 18, 2023 - The committee met in open session via web conference to discuss and make recommendations on the safety and effectiveness of ABRYSVO (Respiratory Syncytial Virus Vaccine), manufactured by Pfizer Inc., with a requested indication, in Biologics License Application # 125768 (STN 125768/0), for the prevention of lower respiratory tract disease and severe lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age by active immunization of pregnant individuals. Agency Action: In the ongoing review of the BLA STN 125768/0, FDA is assessing the following issues discussed at the VRBPAC meeting; the balance between the convincing vaccine efficacy, including against severe lower respiratory tract disease and adverse events, particularly premature delivery/birth, and the gestational age at time of vaccination and considerations for post marketing studies. 6. June 15, 2023-The committee met in open session via web conference to discuss and make recommendations on the selection of strain(s) to be included in the periodic updated COVID-19 vaccines for the 2023-2024 vaccination campaign. Agency Action: FDA has advised

manufacturers who will be updating their COVID-19 vaccines, that they should develop vaccines with a monovalent XBB 1.5 composition. A related web posting was issued by FDA on June 16, 2023.

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 and input lends credibility to regulatory decisions made and helps those decisions stand up to intense public scrutiny. 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 no closed meetings to report for FY2023.

21. Remarks

No reports are required for this committee.

Designated Federal Officer

Sussan Paydar Designated Federal Officer, DSAC, Center for Biologics Evaluation and Research, FDA

Committee Members	Start	End	Occupation	Member Designation
Annunziato, Paula	02/01/2020	01/31/2024	Vice President and Therapeutic Area Head, Vaccines Clinical Research, Merck	Representative Member
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
Cohn, Amanda	02/01/2020	01/31/2024	Chief Medical Officer	Regular Government Employee (RGE) 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
Janes, Holly	06/10/2016	01/31/2025	Associate Member, Fred Hutchinson Cancer Research Center	Special Government Employee (SGE) Member
Kim, David	02/01/2022	01/31/2025	U.S. Department of Health and Human Services	Regular Government Employee (RGE) Member
Monto, Arnold	02/01/2022	01/31/2026	Professor/University of Michigan	Special Government Employee (SGE) Member
Offit, Paul	02/01/2018	01/31/2025	Physician - Children's Hospital of Philadelphia	Special Government Employee (SGE) Member
Pergam, Steven	02/01/2020	01/31/2024	Medical Director	Special Government Employee (SGE) Member
Perlman, Stanley	08/23/2022	01/31/2026	Physician - University of Iowa	Special Government Employee (SGE) Member
Portnoy, Jay	02/01/2022	01/31/2025	Director, Division of Allergy/Asthma/Immunology, The Children’s Mercy Hospital	Representative Member
Rubin, Eric	02/01/2022	01/31/2026	Adjunct Professor, Harvard, TH Chan school of Public Health	Special Government Employee (SGE) Member
Shane, Andrea	02/01/2018	01/31/2025	Physician - Emory University School of Medicine	Special Government Employee (SGE) Member

Number of Committee Members Listed: 16

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?

Number of Recommendations Comments
The Committee made approximately 133 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.

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 a new medical products.

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