2025 Current Fiscal Year Report: Science Board to the Food and Drug Administration

Report Run Date: 07/12/2025 07:45:43 AM

1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2025

3. Committee or Subcommittee	3b. GSA Committee No.
Science Board to the Food and Drug Administration	81

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	06/26/2024	06/26/2026	

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 Science Board makes recommendations to the FDA specifically aimed at enhancing the science and research of the Agency. The Science Board to the Food and Drug Administration (Board) advises the Commissioner in discharging responsibilities as they relate to addressing specific and technically complex scientific issues

of regulatory importance to FDA. The Board consists of a group of senior scientists with exceptionally accomplished backgrounds in evolving areas of new scientific research which will provide advice and further interaction between FDA, industry, academia, and other government agencies on technically complicated issues of regulatory importance. The Science Board has also completed an Agency-wide external peer review of scientific and research programs and will use the findings as a basis for future direction and guidance to the Agency.

20b. How does the Committee balance its membership?

Members are experts in the fields of food science, safety, and nutrition; chemistry; pharmacology; translational and clinical medicine and research; toxicology; biostatistics; medical devices; imaging; robotics; cell and tissue based products; regenerative medicine; public health and epidemiology; international health and regulation; product safety; product manufacturing sciences and quality; and other scientific areas relevant to FDA regulated products such as systems biology, informatics, nanotechnology, and combination products. Members represent academia and industry and include one technically qualified member identified with consumer interests.

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

The Science Board did not meet in FY2024. The Science Board will likely meet twice during FY2025.

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

Members of the Science Board are drawn from the

highest scientific levels of academia, industry, research, and/or clinical practice. Their advice and guidance lend credibility to the agency's science planning and its approach to specific scientific and technical issues.

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

This committee did not hold any closed meetings in FY2024.

21. Remarks

This committee did not meet in FY2024. Time was also devoted to reviewing applications for new nominees, onboarding new members, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was spent in the routine care and maintenance of the committee: the development of a financial report for this website; updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members and providing ethics training. A subcommittee of the Science Board did meet for a site visit in FY2024.

Designated Federal Officer

Rakesh Raghuwanshi DFO, Office of the Chief Scientist

Committee Members	Start	End	Occupation	Member Designation
Afshari, Cynthia	01/01/2015	12/31/2025	Global Head, Preclinical Sciences and Translational Safety, Janssen Research and Development LLC	Special Government Employee (SGE) Member
Bahinski, Anthony	01/01/2015	12/31/2025	Chief Technology Officer, Vivodyne, Inc.	Special Government Employee (SGE) Member

Kowalcyk, Barbara	06/25/2013	12/31/2024	Associate Professor, George Washington University	Special Government Employee (SGE) Member
Nolan, Lisa	01/01/2014	12/31/2024	Dean and Professor, College of Veterinary Medicine, Univ. of Georgia	Special Government Employee (SGE) Member
Reiss, Theodore	09/09/2014	12/31/2025	Executive VP and CMO, Repertoire Immune Medicines	Special Government Employee (SGE) Member
Ryu, Dojin	09/11/2019	12/31/2027	Director, Division of Food, Nutrition, and Exercise Sciences, University of Missouri	Special Government Employee (SGE) Member
Sarwal, Minnie	01/01/2015	12/31/2025	Professor of Surgery and Director, Translational Transplant Research, University of California San Francisco	Special Government Employee (SGE) Member
Tosi, Laura	09/09/2014	12/31/2025	Director, Pediatric Orthopedic Surgeon	Special Government Employee (SGE) Member
Weaver, Connie	01/01/2015	12/31/2025	Distinguished Research Professor, San Diego State Univ.	Special Government Employee (SGE) Member
Xie, Xiang-Qun (Sean)	01/01/2015	12/31/2025	Professor of Pharmaceutical Sciences/Drug Discovery Institute, School of Pharmacy, University of Pittsburgh	Special Government Employee (SGE) Member

Number of Committee Members Listed: 10

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 Science Board supports FDA's strategic priorities by providing advice to the Commissioner in discharging his/her responsibilities as they relate to addressing specific and technically complex scientific issues of regulatory importance to FDA. The Board consists of a group of senior scientists with exceptionally accomplished backgrounds in evolving areas of new scientific research which will provide advice and further interaction between FDA, industry, academia, and other government agencies on technically complicated issues of regulatory importance. The Science Board supports the agency's mission and its strategic plan by strengthening the FDA of today and tomorrow.

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 Science Board 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 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?

147

Number of Recommendations Comments

The number of recommendations reflects the approximate number of recommendations provided to the agency from FY 2003 thru FY 2024.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

85%

% 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, 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 via open, public meetings of the Science Board.

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

The Agency has reordered research priorities and made appropriate shifts in resources to acheive those priorities in response to Science Board recommendations.

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