2025 Current Fiscal Year Report: Nonprescription Drugs 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.
Nonprescription Drugs Advisory Committee	984

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	08/27/2025	08/27/2027	

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	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	$7,488.00
18a(2). Personnel Pmts to Federal Members	$0.00	$1,248.00
18a(3). Personnel Pmts to Federal Staff	$61,802.00	$49,454.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$13,009.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$2,365.00
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)	$15,451.00	$22,249.00
18e. Total Costs	$77,253.00	$95,813.00
19. Federal Staff Support Years (FTE)	0.35	0.25

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates available data concerning the safety and effectiveness of

over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee serves as a forum for FDA to obtain external input regarding issues such as the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also provide feedback on agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

20b. How does the Committee balance its membership?

Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

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

The Committee did not meet during FY-25. It is expected that the Committee will meet 1 time during FY-26.

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 for FDA's consideration as part of its regulatory decision-making. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientists on a full-time basis at a maximum rate of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?
The Committee held no closed meetings during FY-25.

21. Remarks
Although this Committee did not meet in FY-25, considerable time was devoted to appointing members, maintaining associated records for these activities, and streamlining 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. Since the Committee did not meet, no reporting was required. Although the current charter states that the Committee shall hold meetings approximately 1 time a year, this is only an estimation based on data from previous years. The committee chair is currently vacant for this committee.

Designated Federal Officer

Takyiah Stevenson Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Brittain, Kristy	06/01/2023	05/31/2027	Professor, Medical University of South Carolina (MUSC) College of Pharmacy, Clinical Pharmacy Specialist, MUSC Health	Special Government Employee (SGE) Member
Clement, Stephen	06/01/2021	05/31/2025	Associate Professor of Medical Education, University of Virginia School of Medicine; Practicing Physician, INOVA Fairfax Hospital	Special Government Employee (SGE) Member
Collier, W. Greg	06/11/2024	10/31/2027	Regulatory Affairs Consultant	Representative Member
Ginsburg, Diane	06/01/2022	05/31/2026	Clinical Professor, Pharmacy Practice Division; Associate Dean for Healthcare Partnerships The University of Texas at Austin, College of Pharmacy	Special Government Employee (SGE) Member

Roth, Katalin	06/01/2021	05/31/2025	Professor of Medicine, Division of Geriatrics and Palliative Medicine, Medical Faculty Associates The George Washington University School of Medicine and Health Sciences	Special Government Employee (SGE) Member
Walker-Harding, Leslie	06/01/2022	08/11/2025	Ford/Morgan Endowed Professor & Chair, Department of Pediatrics, Associate Dean, University of Washington; Chief Academic Officer & Senior Vice President, Seattle Children’s Hospital	Special Government Employee (SGE) Member

Number of Committee Members Listed: 6

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 Nonprescription Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating

available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner of Food and Drugs either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee will serve as a forum for obtaining external input regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also provide feedback on agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities. This supports the development of safe and effective new medical technologies and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

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

N/A

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 Non-Prescription Drugs Advisory Committee enabled 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?

20

Number of Recommendations Comments

The Committee made 20 recommendations from FY-03 through FY-25.

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, 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 new medical products.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

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