2025 Current Fiscal Year Report: Dermatologic and Ophthalmic 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.
Dermatologic and Ophthalmic Drugs Advisory Committee	108

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	10/07/2024	10/07/2026	

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 Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of dermatologic and ophthalmic disorders. The Committee answers questions that are designed to help the Agency's efforts in completing its review and to reach a final decision

on new drug applications.

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 dermatology, ophthalmology, dentistry, immunology, epidemiology or statistics, and other related professions. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. 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 representative member who is identified with industry interests. There may also be an alternate industry representative.

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

The Committee did not meet during FY-24. It is expected that the Committee will meet 1-2 times during FY-25.

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 FDA regulatory decisions. 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?

The Committee held no closed meetings during FY-24.

21. Remarks

Although this Committee did not meet in FY-24, 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 1-2 times a year, this is only an estimate based on data from previous years. As the FDA convenes advisory committees based on the needs of the Agency, it should not be construed as an exact figure.

Designated Federal Officer

LaToya A. Bonner Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Chodosh, James	09/01/2017	08/31/2025	Professor and Chair, Department of Ophthalmology and Visual Sciences, University of New Mexico School of Medicine	Special Government Employee (SGE) Member
Durham, Todd	09/01/2021	08/31/2025	CONSUMER REPRESENTATIVE; Vice President, Clinical & Outcomes Research, Foundation Fighting Blindness	Special Government Employee (SGE) Member

Green, Brian	09/01/2021	08/31/2025	Associate Professor of Dermatology, Medical Director, Teledermatology, Department of Dermatology, Penn State Hershey Medical Center	Special Government Employee (SGE) Member
Mallbris, Lotus	04/13/2024	10/31/2027	Senior Vice President, Business Unit Leader Japan Immunology, Eli Lilly and Company	Representative Member
Tollefson, Megha	09/01/2019	08/31/2027	Professor, Dermatology and Pediatric and Adolescent Medicine Consultant, Department of Dermatology Mayo Clinic and Mayo Clinic College of Medicine and Science	Special Government Employee (SGE) Member
Xu, Benjamin	02/28/2024	08/31/2027	Assistant Professor of Ophthalmology, USC Roski Eye Institute, Keck Medicine of University of Southern California	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 Dermatologic and Ophthalmic Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the

treatment of dermatologic and ophthalmic disorders and makes appropriate recommendations to the Commissioner of Food and Drugs. 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 Dermatologic and Ophthalmic Drugs Advisory Committee enabled the Agency to obtain required and frequently scarce professional services from the 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?
31

Number of Recommendations Comments
The Committee made 31 recommendations from FY-03 through FY-24.

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 or issues are available publicly when implemented. See Committee website for specific accomplishments: https://www.fda.gov/advisory-committees/human-drug-advisory-committees/dermatologic-and-o

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

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