

2025 Current Fiscal Year Report: Endocrinologic and Metabolic Drugs Advisory Committee

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1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2025

3. Committee or Subcommittee

Endocrinologic and Metabolic Drugs Advisory Committee

3b. GSA Committee No.

855

4. Is this New During Fiscal Year? 5. Current Charter 6. Expected Renewal Date 7. Expected Term Date

No 08/27/2024 08/27/2026

8a. Was Terminated During Fiscal Year? 8b. Specific Termination Authority 8c. Actual Term Date

No

9. Agency Recommendation for Next Fiscal Year 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. Committee 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 Fiscal Year

17a. Open 17b. Closed 0 17c. Partially Closed 0 Other Activities 0 17d. Total 1

Meetings and Dates

Purpose	Start	End
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The Committee discussed new drug application 210934, for sotagliflozin oral tablet, submitted by Lexicon Pharmaceuticals, Inc., for the proposed indication, as an adjunct to insulin therapy, to improve glycemic control in adults with type 1 diabetes mellitus and chronic kidney disease. 10/31/2024 - 10/31/2024

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$6,864.00	\$13,728.00
18a(2). Personnel Pmts to Federal Members	\$1,872.00	\$2,496.00
18a(3). Personnel Pmts to Federal Staff	\$173,845.00	\$58,003.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$11,836.00	\$26,225.00
18b(2). Travel and Per Diem to Federal Members	\$1,728.00	\$0.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$1,389.00
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)	\$49,054.00	\$25,801.00
18e. Total Costs	\$245,199.00	\$127,642.00

19. Federal Staff	1.10	0.33
Support Years (FTE)		

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders, and makes appropriate recommendations to the Commissioner of Food and Drugs.

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 endocrinology, metabolism, statistics, and related specialties. 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 held one meeting in FY-25. On October 31, 2024, the Endocrinologic and Metabolic Drugs Advisory Committee met to

discuss new drug application 210934, for sotagliflozin oral tablet, submitted by Lexicon Pharmaceuticals, Inc., for the proposed indication, as an adjunct to insulin therapy, to improve glycemic control in adults with type 1 diabetes mellitus and chronic kidney disease. The Committee discussed the clinical benefits of sotagliflozin oral tablets on hemoglobin A1c (A1C) in patients with estimated glomerular filtration rates (eGFR) below 60 mL/min, and whether these benefits are greater in patients with type 1 diabetes (T1D) and chronic kidney disease (CKD) compared to those without CKD. Safety concerns were raised regarding the incidence and severity of diabetic ketoacidosis (DKA) in T1D patients with CKD treated with sotagliflozin. Following deliberation, the Committee voted 11 to 3 that the available data did not demonstrate that the benefits of sotagliflozin outweigh the risks for the indication of improving glycemic control in patients with T1D and CKD. It is expected that the Committee will meet 2-4 times 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 to FDA for consideration in 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 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

There were no reports required for this Committee in FY-25. Although the current charter states that the Committee shall hold meetings approximately 2-4 times a year, this is only an estimation 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. The committee chair is currently vacant for this committee.

Designated Federal Officer

LaToya Bonner Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Chrischilles, Elizabeth	10/31/2024	10/31/2024	University of Iowa, College of Public Health	Special Government Employee (SGE) Member
Drake, Matthew	07/01/2022	06/30/2026	Associate Professor, Chair - Metabolic Bone Disease Core Group, Division of Endocrinology, Mayo Clinic	Special Government Employee (SGE) Member
Everett, Brendan	10/31/2024	10/31/2024	College of Medicine Associate Professor of Medicine, Harvard Medical School, Cardiovascular Medicine Brigham and Women's Hospital	Special Government Employee (SGE) Member
Greevy, Robert	07/01/2022	06/30/2026	Associate Professor, Department of Biostatistics; Director, Health Services Research Biostatistics, Vanderbilt University Medical Center	Special Government Employee (SGE) Member

Irony, Ilan	07/08/2024	10/31/2027	Senior Director, Global Regulatory Lead, Janssen Research and Development, Johnson and Johnson Family of Companies	Representative Member
Konstam, Marvin	10/31/2024	10/31/2024	Chief Physician Executive, The CardioVascular Center, Tufts Medical Center Professor of Medicine, University of Colorado, Anschutz Medical Campus,	Special Government Employee (SGE) Member
Low Wang, Cecilia	07/01/2021	06/30/2025	Clinician-Scientist, CPC Clinical Research Director, Glucose Management Team, University of Colorado Hospital Mathematical Statistician, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, NIH	Special Government Employee (SGE) Member
Nason, Martha	10/31/2024	10/31/2024	Adjunct Professor of Medicine, NYU Robert I. Grossman School of Medicine	Regular Government Employee (RGE) Member
Newman, Connie	10/31/2024	10/31/2024	Physician Owner, The Diabetes and Endocrine Wellness Center, LLC	Special Government Employee (SGE) Member
Onumah, Barbara	10/31/2024	10/31/2024	Senior Scientific Advisor Program Director Clinical Kidney Genetics and Chronic Kidney Disease, The National Institute of Diabetes and Digestive and Kidney Diseases, NIH	Regular Government Employee (RGE) Member
Parsa, Afshin	10/31/2024	10/31/2024		

Roy-Chaudhury, Prabir	10/31/2024	10/31/2024	Eminent Professor and Co-Director University of North Carolina Kidney Center	Regular Government Employee (RGE) Member
Seliger, Steve	10/31/2024	10/31/2024	Associate Professor Department of Medicine Division of Nephrology University of Maryland School of Medicine	Regular Government Employee (RGE) Member
Shoben, Abigail	10/31/2024	10/31/2024	Associate Professor, Division of Biostatistics College of Public Health, The Ohio State University	Special Government Employee (SGE) Member
Tibbits, Paul	10/31/2024	10/31/2024	Advocacy and Communications Leader	Special Government Employee (SGE) Member
Wang, Thomas	07/01/2022	06/30/2026	Professor and Chair of Medicine, Donald W. Seldin Distinguished Chair in Internal Medicine, UT Southern Medical Center	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 tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Endocrinologic and Metabolic 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 endocrinologic and metabolic diseases and makes appropriate recommendations to the Commissioner of the Food and Drug Administration. 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 Endocrinologic and Metabolic Drugs 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?

55

Number of Recommendations Comments

The Committee made 55 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

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	<input checked="" type="checkbox"/>
Reallocated resources	<input checked="" type="checkbox"/>
Issued new regulation	<input checked="" type="checkbox"/>
Proposed legislation	<input checked="" type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

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	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>
Online Committee Web Site	<input checked="" type="checkbox"/>
Online GSA FACA Web Site	<input checked="" type="checkbox"/>
Publications	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

Access Comments

N/A