2025 Current Fiscal Year Report: Endocrinologic and Metabolic 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.
Endocrinologic and Metabolic Drugs Advisory Committee	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 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 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-24. On May 24, 2024, the Committee discussed the safety and efficacy of biologics license application (BLA) 761326 for NNC0148-0287 injection (insulin icodec), a long-acting insulin analog product, submitted by Novo Nordisk. The proposed indication is to improve glycemic control in adults with diabetes mellitus. The majority of the Committee (7 Noes, 4 Yeses, 0 Abstention) voted “No”, indicating the Applicant did not demonstrate that the benefits of insulin icodec outweigh its risks for improving glycemic control in adults with T1D. Agency Action: The Agency is currently evaluating recommendations made during the meeting. It is expected that the Committee will meet 2-4 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. 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-24.

21. Remarks
There were no reports required for this Committee in FY-24. 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 regarding 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
Drake, Matthew	07/01/2022	06/30/2026	Associate Professor, Chair - Metabolic Bone Disease Core Group, Division of Endocrinology, Mayo Clinic College of Medicine	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
Low Wang, Cecilia	07/01/2021	06/30/2025	Professor of Medicine, University of Colorado, Anschutz Medical Campus, Clinician-Scientist, CPC Clinical Research Director, Glucose Management Team, University of Colorado Hospital	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: 5

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-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

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 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