

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

Report Run Date: 05/18/2025 05:43:25 AM

### 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?

No

### 5. Current Charter

08/27/2024 08/27/2026

### 6. Expected Renewal Date

### 7. Expected Term Date

### 8a. Was Terminated During Fiscal Year?

No

### 8b. Specific Termination Authority

### 8c. Actual Term Date

### 9. Agency Recommendation for Next Fiscal Year

Continue

### 10a. Legislation Req to Terminate?

Not Applicable

### 10b. Legislation Pending?

Not Applicable

### 11. Establishment Authority Authorized by Law

### 12. Specific Establishment Authority

21 U.S.C. 394

### 13. Effective Date

11/28/1990

### 14. Committee Type

Continuing

### 14c. Presidential?

No

### 15. Description of Committee Scientific Technical Program

Advisory Board

### 16a. Total Number of Reports

No Reports for  
this Fiscal Year

### 17a. Open

0 17b. Closed0 17c. Partially Closed0 Other Activities0 17d. Total0

### Meetings and Dates

No Meetings

	Current FY	Next FY
<b>18a(1). Personnel Pmts to Non-Federal Members</b>	\$0.00	\$0.00
<b>18a(2). Personnel Pmts to Federal Members</b>	\$0.00	\$0.00
<b>18a(3). Personnel Pmts to Federal Staff</b>	\$0.00	\$0.00
<b>18a(4). Personnel Pmts to Non-Member Consultants</b>	\$0.00	\$0.00
<b>18b(1). Travel and Per Diem to Non-Federal Members</b>	\$0.00	\$0.00
<b>18b(2). Travel and Per Diem to Federal Members</b>	\$0.00	\$0.00
<b>18b(3). Travel and Per Diem to Federal Staff</b>	\$0.00	\$0.00
<b>18b(4). Travel and Per Diem to Non-member Consultants</b>	\$0.00	\$0.00
<b>18c. Other(rents,user charges, graphics, printing, mail, etc.)</b>	\$0.00	\$0.00
<b>18d. Total</b>	\$0.00	\$0.00
<b>19. Federal Staff Support Years (FTE)</b>	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

<b>Committee Members</b>	<b>Start</b>	<b>End</b>	<b>Occupation</b>	<b>Member Designation</b>
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
			Associate Professor, Department of Biostatistics; Director, Health Services Research Biostatistics, Vanderbilt University Medical Center	
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

**Number of Committee Members Listed: 5**

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	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input checked="" type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input type="checkbox"/>
Increased customer satisfaction	<input checked="" type="checkbox"/>
Implementation of laws or regulatory requirements	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

**Outcome Comments**

N/A

**What are the cost savings associated with this committee?**

	Checked if Applies
None	<input type="checkbox"/>
Unable to Determine	<input checked="" type="checkbox"/>
Under \$100,000	<input type="checkbox"/>
\$100,000 - \$500,000	<input type="checkbox"/>
\$500,001 - \$1,000,000	<input type="checkbox"/>
\$1,000,001 - \$5,000,000	<input type="checkbox"/>
\$5,000,001 - \$10,000,000	<input type="checkbox"/>
Over \$10,000,000	<input type="checkbox"/>
Cost Savings Other	<input type="checkbox"/>

**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	<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