2025 Current Fiscal Year Report: Gastrointestinal 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.
Gastrointestinal Drugs Advisory Committee	874

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	03/03/2024	03/03/2026	

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. Other(rents,user charges, graphics, printing, mail, etc.)	$0.00	$0.00
18d. Total	$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 available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal diseases and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are authorities in the fields of gastroenterology, endocrinology, surgery, clinical

pharmacology, physiology, pathology, liver function, motility, esophagitis, and statistics. The committee includes one technically qualified voting member who is identified with consumer interests. The Committee may include one non-voting member who is identified with industry interests.

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

In FY-24, the Committee held one meeting. On September 13, 2024, the Gastrointestinal Drugs Advisory Committee discussed supplemental new drug application (sNDA) 207999 S-011, for OCALIVA (obeticholic acid) 5 mg titrated to 10 mg oral tablets, administered once a day, submitted by Intercept Pharmaceuticals, Inc., to fulfill the accelerated approval postmarketing requirements specified in the OCALIVA approval letter dated May 27, 2016. The sNDA included data proposed to describe and verify clinical benefit for the indication of reducing the risk of death, liver transplant, and hepatic decompensation in adult patients with primary biliary cholangitis without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with ursodeoxycholic acid (UDCA) with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA. The Committee members were in near unanimous agreement (13 to 1) that the available evidence does not verify the benefit of OCA on clinical outcomes in the USPI-labeled population. In providing support for their vote, members who voted “No” cited inconclusive results from study 302, noting the trial did not meet its primary endpoint and the numerous challenges faced by this study including crossovers due to OCA’s commercial availability. The majority of Committee members (1 yes, 10 no, 3 abstain) also voted that

OCA’s benefit-risk profile is not favorable in the USPI-labeled population. Members who voted “No” cited the unproven benefit and significant safety concerns of OCA in providing the rationale for their vote. The Agency is still reviewing recommendations made at the meeting. It is expected that the Committee will meet two to three 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 that FDA considers as part of its regulatory decision-making process. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientist 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 2-3 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. It is expected that the Committee will meet 2-3 times during FY-25.

Designated Federal Officer
Jessica Seo Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation

Assis, David	04/23/2022	06/30/2025	Yale School of Medicine, Department of Internal Medicine, Section of Digestive Diseases	Special Government Employee (SGE) Member
Chang, Lin	09/16/2021	06/30/2025	Professor of Medicine, David Geffen School of Medicine at UCLA	Special Government Employee (SGE) Member
Coffey, Christoper	06/27/2024	06/30/2026	Professor and Director Clinical Trials Statistical and Data Management Center Department of Biostatistics University of Iowa	Special Government Employee (SGE) Member
Crandall, Wallace	02/28/2024	10/31/2027	Associate Vice President – Medical, Immunology GI Therapeutic Area Head Eli Lilly and Company	Representative Member
Heller, Theo	09/09/2024	06/30/2028	Chief, Translational Hepatology Section, Senior Investigator, Liver Diseases Branch National Institute of Diabetes and Digestive Kidney Diseases, National Institutes of Health	Regular Government Employee (RGE) Member
Lebwohl, Benjamin	07/01/2017	06/30/2025	Professor of Medicine and Epidemiology; Director of Clinical Research, Celiac Disease Center, Columbia University College of Physicians & Surgeons	Special Government Employee (SGE) Member
Lee, Brian	09/09/2024	06/30/2028	Associate Professor of Medicine Division of Gastrointestinal and Liver Diseases, Keck School of Medicine University of Southern California	Special Government Employee (SGE) Member

McVey, Joy	03/19/2018	06/30/2025	CONSUMER REPRESENTATIVE - Program Manager, Special Volunteer Services, Emory Healthcare; Principal Consultant, Simply Joy, LLC	Special Government Employee (SGE) Member

Number of Committee Members Listed: 8

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 Gastrointestinal 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 gastrointestinal diseases 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

NA

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 Gastrointestinal 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 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?

26

Number of Recommendations Comments

The Committee made 26 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 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 product.

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

No

Grant Review Comments

NA

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

NA