

2024 Current Fiscal Year Report: Gastrointestinal Drugs Advisory Committee

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1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2024

3. Committee or Subcommittee

Gastrointestinal Drugs Advisory Committee

3b. GSA Committee No.

874

4. Is this New During Fiscal Year?

No

5. Current Charter

03/03/2022 03/03/2024

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. Closed

0

17c. Partially Closed

0

Other Activities

0

17d. Total

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-23, the Committee held one meeting. On May 19, 2023, the Gastrointestinal Drugs Advisory Committee met to discuss new drug application (NDA) 212833, obeticholic acid (OCA) 25mg oral tablets, submitted by Intercept Pharmaceuticals, Inc., for the treatment of pre-cirrhotic liver fibrosis due to nonalcoholic steatohepatitis (NASH). A majority of members (2 Yeses and 12 Noes) voted that the benefits of OCA 25 mg did not weigh the risks in NASH patients with Stage 2 or 3 fibrosis. Agency Action: The Agency is reviewing recommendations made at the meeting. It is expected that the Committee will meet two to three times during FY-24.

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 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-23.

21. Remarks

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. There were no reports required for this Committee in FY-23

Designated Federal Officer

Rhea Bhatt Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Albrecht, Helmut	11/01/2019	10/31/2023	President, H2A Associates, LLC Chief Scientific Officer, Alitair Pharmaceuticals, Inc.	Representative Member
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
Khurana, Sandeep	07/01/2020	06/30/2024	Professor of Medicine, Geisinger Commonwealth School of Medicine	Special Government Employee (SGE) Member
Lai, Jennifer	08/06/2018	06/30/2026	Associate Professor of Medicine, Endowed Professorship of Liver Health & Transplantation, Division of Gastroenterology/Hepatology, University of California–San Francisco	Special Government Employee (SGE) Member
Lebwohl, Benjamin	07/01/2017	06/30/2025	Associate Professor of Medicine and Epidemiology; Director of Clinical Research, Celiac Disease Center, Columbia University College of Physicians & Surgeons	Special Government Employee (SGE) Member
McVey Hugick, Joy	09/16/2021	06/30/2025	CONSUMER REPRESENTATIVE - Principal Consultant, Simply Joy, LLC	Special Government Employee (SGE) Member
Streett, Sarah	07/01/2020	06/30/2024	Director of Inflammatory Bowel Disease Education, Clinical Professor of Medicine, Stanford University School of Medicine	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	<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

NA

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 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?

25

Number of Recommendations Comments

The Committee made 25 recommendations from FY-03 through FY-23.

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	<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 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	<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

NA