

2023 Current Fiscal Year Report: Arthritis Advisory Committee

Report Run Date: 03/29/2024 02:12:56 PM

1. Department or Agency

Department of Health and Human
Services

2. Fiscal Year

2023

3. Committee or Subcommittee

Arthritis Advisory Committee

3b. GSA Committee

No.

223

4. Is this New During Fiscal Year?

5. Current Charter

6. Expected Renewal Date

7. Expected Term Date

No 04/05/2022 04/05/2024

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	\$13,508.00
18a(2). Personnel		
Pmts to Federal Members	\$0.00	\$4,912.00
18a(3). Personnel	\$168,232.00	\$186,101.00
Pmts to Federal Staff		
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.)	\$42,058.00	\$65,293.00
18d. Total	\$210,290.00	\$269,814.00
19. Federal Staff Support Years (FTE)	1.10	1.10

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 arthritis, rheumatism, and related diseases, and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in arthritis, rheumatology, pediatrics, immunology, allergy, epidemiology, clinical pharmacology, biostatistics, and related specialties. The Committee also includes a technically qualified voting member identified with consumer interests. The Committee may include one non-voting member identified with industry interests.

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

The Committee did not meet during FY-23. It is expected that the Committee will meet 2-3 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 this Committee did not meet in FY-23, considerable time was devoted to appointing members, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was spent in the routine care and maintenance of the Committee:

the development of a financial report for this website; updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members and providing ethics training. Since the Committee did not meet, no reporting was required. 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.

Designated Federal Officer

Jessica Seo Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Chung, Sharon	10/28/2021	09/30/2025	Professor of Clinical Medicine, Division of Rheumatology, Department of Medicine; Director, Clinical and Translational Medicine, Immune Tolerance Network, University of California, San Francisco	Special Government Employee (SGE) Member
Dellaripa, Paul	10/01/2020	09/30/2024	Associate Professor of Medicine, Harvard Medical School; Attending Physician, Brigham and Women's Hospital	Special Government Employee (SGE) Member
Honczarenko, Marek	11/01/2019	10/31/2023	Senior Vice President, Clinical Sciences, GlaxoSmithKline (GSK)	Representative Member
Johnson, Hetlena	12/05/2019	09/30/2023	CONSUMER REPRESENTATIVE - Lupus Awareness Advocate	Special Government Employee (SGE) Member

Klein-Gitelman, Marisa	10/01/2021	09/30/2025	Head, Division of Rheumatology, Ann & Robert H. Lurie Children's Hospital of Chicago; Professor of Pediatrics, Northwestern University Feinberg School of Medicine Mathematical Statistician, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health Durham Veterans Affairs Medical Center; Professor of Medicine and Immunology, Duke University Medical Center	Special Government Employee (SGE) Member
Nason, Martha	10/01/2018	09/30/2026	Chief, Rheumatology Section, Dallas Veterans Affairs Medical Center; Professor of Medicine, University of Texas Southwestern Medical Center	Regular Government Employee (RGE) Member
Pisetsky, David	12/05/2019	09/30/2023	Chief, Division of Rheumatology, Veterans Affairs Pittsburgh Healthcare System; Clinical Associate Professor of Medicine, University of Pittsburgh	Regular Government Employee (RGE) Member
Reimold, Andreas	10/01/2022	09/30/2026	Staff Physician, Birmingham VA Medical Center; Professor of Medicine and Epidemiology with Tenure, University of Alabama at Birmingham	Regular Government Employee (RGE) Member
Richards, John	10/01/2017	09/30/2025	Professor of Medicine, University of Pittsburgh	Regular Government Employee (RGE) Member
Singh, Jasvinder	10/01/2019	09/30/2023	Professor of Medicine and Epidemiology with Tenure, University of Alabama at Birmingham	Regular Government Employee (RGE) Member

Weisman, Michael	10/01/2020	09/04/2024	Distinguished Professor of Medicine Emeritus, David Geffen School of Medicine at UCLA; Professor of Medicine Emeritus, Cedars Sinai Medical Center	Special Government Employee (SGE) Member
			Associate Professor of Medicine, Icahn School of Medicine at Mount Sinai	Special Government Employee (SGE) Member
Wiesendanger, Margrit	10/01/2019	09/30/2023		

Number of Committee Members Listed: 12

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 Arthritis 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 arthritis, rheumatism, and related 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

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 Arthritis 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 not otherwise available to the Agency; and to obtain the services of these experts only on an as needed bases 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?

40

Number of Recommendations Comments

The Committee made 40 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 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 or 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

☐

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