2024 Current Fiscal Year Report: Arthritis Advisory Committee

Report Run Date: 04/27/2024 04:28:33 AM

1. Department or Agency 2. Fiscal Year

Department of Health and Human

Services

2024

3b. GSA Committee
3. Committee or Subcommittee

No.

Arthritis Advisory Committee 223

4. Is this New During 5. Current 6. Expected 7. Expected Fiscal Year? Charter Renewal Date Term Date

No 04/05/2022 04/05/2024

8a. Was Terminated During 8b. Specific Termination Authority 8c. Actual Term Date

No

9. Agency 10b.

Recommendation for Next Req to Terminate?

FiscalYear Legislation Pending?

Continue Not Applicable Not Applicable

11. Establishment Authority Authorized by Law

12. Specific 13. 14.

Establishment Effective Commitee Presidential?

Authority Date Type

21 U.S.C. 394 11/28/1990 Continuing No

15. Description of Committee Scientific Technical Program

Advisory Board

16a. Total

No Reports for this FiscalYear

Reports

17a.

Open 0 17b. Closed 0 17c. Partially Closed 0 Other Activities 0 17d. Total 0

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Meetings and Dates

No Meetings

Current Next

FY 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 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

Toolia Goo Boolghalaa i Gaorai Gillooi				
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

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	Special Government Employee (SGE) Member
Nason, Martha	10/01/2018	09/30/2026	Statistician, Division of Clinical Research, National	Regular Government Employee (RGE) Member
Reimold, Andreas	10/01/2022	09/30/2026	Rheumatology Section, Dallas Veterans Affairs Medical Center; Professor of Medicine, University of Texas Southwestern Medical Center Chief, Division	-
Richards, John	10/01/2017	09/30/2025	of Rheumatology, Veterans Affairs Pittsburgh Healthcare System; Clinical Associate Professor of Medicine, University of Pittsburgh	Regular Government Employee (RGE) Member

Distinguished Professor of Medicine

Emeritus, David

Geffen School Special

10/01/2020 09/04/2024 UCLA;

of Medicine at Government UCLA; Employee

Professor of (SGE) Member Medicine

Medicine
Emeritus,
Cedars Sinai
Medical Center

Number of Committee Members Listed: 8

Narrative Description

Weisman,

Michael

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

✓

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 com	nmittee?
Check	ked if Applies
None	
Unable to Determine	✓
Under \$100,000	
\$100,000 - \$500,000	

Cost Savings Comments

\$5,000,001 - \$10,000,000

\$500,001 - \$1,000,000 \$1,000,001 - \$5,000,000

Over \$10,000,000

Cost Savings Other

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 <u>Number</u> of recommendations produced by this committee for the life of the committee?

40

The Committee made 40 recommendations from FY-03 through FY-23.

What is the approximate <u>Percentage</u> of the will be <u>Fully</u> implemented by the agency?		
% 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?		
% of Recommendations Partially Implementation of an advisory committee is pure most often accepts the recommendations from advisory in nature, and the Agency has the organization.	rely advisory in nature. Although the FDA om its committees, the advice is purely	
Does the agency provide the committee vimplement recommendations or advice of Yes № No Not Applicable □		
Agency Feedback Comments When appropriate, information is made avail documents or other general matters or issue	lable to the public. Actions related to guidance es 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	\checkmark	
Reallocated resources	✓	
Issued new regulation	✓	
Proposed legislation	✓	

Approved grants or other payments

Other

FDA approves or chooses not to approve ne	w medical products.
Is the Committee engaged in the review o No	f applications for grants?
Grant Review Comments N/A	
How is access provided to the information	n 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	

Action Comments

Access Comments

N/A