2015 Current Fiscal Year Report: Antiviral Drugs Advisory Committee

Report Run Date: 04/17/2024 11:59:51 PM

1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2015

3. Committee or Subcommittee	3b. GSA Committee No.
Antiviral Drugs Advisory Committee	789

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	02/15/2013	02/15/2015	02/15/2015

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
Yes		02/15/2015

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Terminate	No	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	$42,839.00	$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.)	$10,710.00	$0.00
18d. Total	$53,549.00	$0.00
19. Federal Staff Support Years (FTE)	0.35	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 investgational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), human immunodeficiency virus related illnesses, and other viral, fungal, and mycobacterial infections 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.

20b. How does the Committee balance its membership?

Members are authorities in the fields of clinical pharmacology, internal medicine, infectious diseases, microbiology, virology, psychiatry, statistics, epidemiology, immunology, pediatrics, hematology, and related specialties. 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?

The committee did not meet in FY-15.

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 regulatory decisions. The alternate means of obtaining this advice would be to hire large numbers of scientists on a full time basis at great expense to the government.

20e. Why is it necessary to close and/or partially closed committee meetings?

There were no closed meetings to report for FY-15.

21. Remarks

The committee is not required to do any reporting for FY-15. Although this committee did not meet in FY-15, considerable time was devoted to the work involved to terminate the committee and members. The committee was terminated on February 15, 2015.

Designated Federal Officer

Jennifer Shepherd DFO

Committee Members	Start	End	Occupation	Member Designation
Aronsohn, Andrew	11/01/2013	02/15/2015	Assistant Professor of Medicine,University of Chicago Medical Center	Special Government Employee (SGE) Member
Connick, Elizabeth	05/17/2011	10/31/2014	Professor of Medicine, University of Colorado Denver, Division of Infectious Diseases	Special Government Employee (SGE) Member
Corbett, Amanda	04/11/2012	02/15/2015	Clinical Associate Professor, University of North Carolina, Eshelman School of Pharmacy	Special Government Employee (SGE) Member
Daskalakis, Demetre	04/16/2012	02/15/2015	Associate Professor, Medical Director HIV Program, New York University School of Medicine	Special Government Employee (SGE) Member
Follmann, Dean	11/01/2013	02/15/2015	Assistant Director for Biostatistics, National Institute of Allergy and Infectious Diseases	Regular Government Employee (RGE) Member
Friedman, Lawrence	03/20/2013	02/15/2015	Chair, Department of Medicine, Newton-Wellesley Hospital	Special Government Employee (SGE) Member
Giordano, Thomas	05/17/2011	10/31/2014	Associate Professor of Medicine, Baylor College of Medicine	Special Government Employee (SGE) Member
Glenn, Jeffrey	05/17/2011	10/31/2014	Associate Professor of Medicine, Division of Gastroenterology and Hepatology, Stanford University, Division of Gastroenterology and Hepatology	Special Government Employee (SGE) Member
Honegger, Jonathan	11/01/2013	02/15/2015	Assistant Professor, Department of Pediatrics, The Ohio State University School of Medicine, Nationwide Children's Hospital	Special Government Employee (SGE) Member

Isaacs, Robin	04/04/2012	02/15/2015	Vice President, Vaccine & Infectious Disease Clinical Research, Merck Inc.	Representative Member
Lo Re, Vincent	11/01/2013	02/15/2015	Assistant Professor of Medicine and Epidemiology, University of Pennsylvania	Special Government Employee (SGE) Member
Mark, Karen	04/11/2012	02/15/2015	Chief, Office of AIDS, California Department of Public Health	Special Government Employee (SGE) Member
Murata, Yoshihiko	05/17/2011	10/31/2014	University of Rochester School of Medicine	Special Government Employee (SGE) Member
Raymond, Daniel	04/11/2012	02/15/2015	CONSUMER REPRESENTATIVE, Director of Policy, Harm Reduction Coalition	Special Government Employee (SGE) Member

Number of Committee Members Listed: 14

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 Antiviral 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 acquired immune deficiency syndrome, human immunodeficiency virus related illnesses, and other viral, fungal and mycobacterial infections, 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 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 Anti-Viral Drugs Advisory Committee enabled 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?
33

Number of Recommendations Comments
The commmittee made 33 recommendations from FY03 to FY15 - see question 20a of the annual report for specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
80%

% 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, and therefore, the Agency has the option of not implementing the advice.

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
It usually does. 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	✓
Reallocated resources	
Issued new regulation	✓
Proposed legislation	
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