2018 Current Fiscal Year Report: Peripheral and Central Nervous System Drugs Advisory Committee

Report Run Date: 06/19/2019 03:44:51 PM

1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018

3. Committee or Subcommittee	3b. GSA Committee No.
Peripheral and Central Nervous System Drugs Advisory Committee	990

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	06/04/2018	06/04/2020	

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 1 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start	End
The committee discussed new drug application (NDA) 210365, cannabidiol oral solution, sponsored by GW Pharmaceuticals, for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.	04/19/2018	04/16/2018

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$3,143.00	$5,468.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$173,110.00	$175,743.00
18a(4). Personnel Pmts to Non-Member Consultants	$3,143.00	$2,734.00
18b(1). Travel and Per Diem to Non-Federal Members	$3,837.00	$5,504.00
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	$4,743.00	$3,404.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$44,526.00	$45,197.00
18d. Total	$232,502.00	$238,050.00
19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of neurological diseases and makes appropriate recommendations to the Commissioner of the Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in the fields of neurology, neuropharmacology, neuropathology, otolaryngology, epidemiology, statistics or related specialties. The committee has one technically qualified member identified with consumer interests. In addition to the voting members, the Committee includes one non-voting member who is identified with industry interests.

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

The committee met once during FY-18. On April 19, 2018, the committee discussed new drug application (NDA) 210365, cannabidiol oral solution, sponsored by GW Pharmaceuticals, for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. The committee unanimously (13 members) agreed that the benefit-risk profile of cannabidiol was favorable for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome in patients 2 years of age and older. The committee members agreed that efficacy was well demonstrated in the studies and that the safetyconcerns could be managed with labeling, education and monitoring. Agency Action: On June 25, 2018, the Agency approved Epidiolex (cannabidiol) oral solution for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. It is expected that the committee will meet two to three times during FY-19.

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 committee helps the regulatory decisions withstand intense public scrutiny. The means of obtaining this advice would involve the recruitment of large numbers of scientists on a full-time basis at maximum rates of compensation.

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

The committee held no closed meetings during FY-18.

21. Remarks

The committee is not required to do any reporting for FY-18.

Designated Federal Officer

Yinghua S Wang DFO

Committee Members	Start	End	Occupation	Member Designation
Alexander, George	06/17/2014	01/31/2019	Associate Professor of Epidemiology and Medicine, Johns Hopkins School of Public Health	Special Government Employee (SGE) Member
Cudkowicz, Merit	03/18/2016	01/31/2020	Chief of Neurology, Massachusetts General Hospital, Julieanne Dorn Professor of Neurology, Harvard Medical School	Special Government Employee (SGE) Member
Fountain, Nathan	02/01/2018	01/31/2022	Professor of Neurology, University of Virginia	Special Government Employee (SGE) Member
Gonzales, Nicole	06/17/2014	01/31/2018	Associate Professor, University of Texas-Houston Medical School, Department of Neurology – Stroke Program	Special Government Employee (SGE) Member
Gordon, Mark	03/18/2016	10/31/2019	Senior Director, Clinical Development, CNS, Movement Disorders, Teva Pharmaceuticals	Representative Member
Green, Mark	02/01/2016	01/31/2020	Professor of Neurology, Anesthesiology, and Rehabilitation Medicine, Director of Headache and Pain Medicine, Icahn School of Medicine at Mt Sinai	Special Government Employee (SGE) Member
Knopman, David	02/01/2018	01/31/2022	Professor of Neurology, Mayo Clinic	Special Government Employee (SGE) Member
Kryscio, Richard	04/21/2016	01/31/2020	Professor, Statistics and Biostatistics, University of Kentucky	Special Government Employee (SGE) Member
Onyike, Chiadi	02/01/2015	01/31/2019	Associate Professor of Psychiatry and Behavioral Sciences, The Johns Hopkins University of Medicine	Special Government Employee (SGE) Member
Ovbiagele, Bruce	06/17/2014	01/31/2018	Professor and Chairman of Neurology, Medical University of South Carolina	Special Government Employee (SGE) Member
Perlmutter, Joel	02/01/2016	01/31/2020	Elliot Stein Family Professor of Neurology, Professor of Radiology, Neuroscience, Physical Therapy & Occupational Therapy, Washington University School of Medicine	Special Government Employee (SGE) Member

Number of Committee Members Listed: 11

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 Peripheral and Central Nervous System Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic 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 the 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 Peripheral and Central Nervous System 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?

26

Number of Recommendations Comments

The committee made 26 recommendations from FY-03 through FY-18. 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?

77%

% 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?

8%

% 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