2016 Current Fiscal Year Report: Transmissible Spongiform Encephalopathies Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2016

3. Committee or Subcommittee	3b. GSA Committee No.
Transmissible Spongiform Encephalopathies Advisory Committee	2026

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	06/09/2014	06/09/2016	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
Yes	41 CFR Sec. 102-3.30(b)	06/09/2016

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	$132,608.00	$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	$6.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	$0.00	$0.00
18d. Other (all other funds not captured by any other cost category)	$33,152.00	$0.00
18e. Total Costs	$165,766.00	$0.00
19. Federal Staff Support Years (FTE)	0.80	0.00

20a. How does the Committee accomplish its purpose?

The Committee reviewed and evaluated available scientific data concerning the safety of products which may be at risk for the transmission of spongiform encephalopathies (TSE). The committee was terminated on June 9, 2016.

20b. How does the Committee balance its

membership?
Members were selected from academic and clinical practice settings and included authorities in the areas of clinical and administrative medicine, hematology, virology, neurovirology, neurology, infectious diseases, immunology, transfusion medicine, surgery, internal medicine, biochemistry, biostatistics, epidemiology, biological and physical sciences, sociology/ethics, public health, and other related professions. One member was technically qualified and identified with consumer interests. In addition, the Committee included a non-voting member to represent industry's interests. The committee was terminated on June 9, 2016.

20c. How frequent and relevant are the Committee Meetings?
The Committee did not meet during this reporting period. The committee was terminated on June 9, 2016.

20d. Why can't the advice or information this committee provides be obtained elsewhere?
The committee was terminated on June 9, 2016. During the active period of the committee members of the committee were drawn from academia, research, clinical practice, consumer organizations, product recipients, and healthcare providers. Their advice and input was available to provide credibility to regulatory decisions made and was representative of the knowledge and experience as needed from informed sources. The alternate means of obtaining this advice would have involved 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?

No meetings were closed during this reporting period.

21. Remarks

No reports were required from this committee. Although this Committee did not meet in FY 2016 and was terminated on June 9, 2016, time was spent in the routine care and maintenance of the Committee; updating the roster and number of vacancies on the FDA website; completing the annual ethics report; reviewing financial disclosures of current members; and providing ethics training.

Designated Federal Officer

Bryan Hatfield Emery Center for Biologics Evaluation and Research, FDA

Committee Members	Start	End	Occupation	Member Designation
Belay, Ermias	08/09/2012	06/09/2016	Assoc Dir Epidemiologic Sciences, Div Viral & Ricketsial Dis, CDC, Atlanta	Regular Government Employee (RGE) Member
Caughey, Bryon	06/04/2013	06/09/2016	Chief, TSE/Prion, Rocky Mountain Labs, NIAID, Hamilton, MT	Regular Government Employee (RGE) Member
Detwiler, Linda	11/11/2011	06/09/2016	Veterinarian, Private Practice, Red Bank, NJ	Special Government Employee (SGE) Member
Ghetti, Bernardino	04/01/2015	06/09/2016	Neuropathology expert, Distinguished Professor, Division of neuropathology, Indiana University School of Medicine	Special Government Employee (SGE) Member
Goeldner, Dean	08/09/2012	06/09/2016	Veterinary Medical Officer, USDA, APHIS, Vet Services, Riverdale, MD	Regular Government Employee (RGE) Member

Huskie, David	08/09/2012	06/09/2016	Registed Nurse, Veterans Affairs Medical Center, Albany, NY	Regular Government Employee (RGE) Member
Kascsak, Richard	06/04/2013	06/09/2016	Head, Monoclonal Antibody Facility, NY State Inst. Basic Res., Staten Island, NY	Special Government Employee (SGE) Member
Kranitz, Florence	04/11/2012	06/09/2016	CONSUMER REPRSENTTIVE. President, Creutzfeldt-Jakob Diseases Foundation, New York, NY	Special Government Employee (SGE) Member
Lee, Douglas	04/15/2009	06/09/2016	Vice President, Pathogen Safety and Research, Grifolds, Inc., Raleigh, NC	Representative Member
Leviyang, Sivan	07/01/2013	06/09/2016	Assist. Prof., Georgetown Univ., Washington, DC	Special Government Employee (SGE) Member
Roos, Raymond	11/24/2014	06/09/2016	Neuropsychiatry Expert, Neurological Science Professor, Department of Neurology, University of Chicago	Special Government Employee (SGE) Member
Safar, Jiri	11/24/2014	06/09/2016	Prion Neurology expert, Associate Professor, Departments of Pathology and Neurology, Co-Director National Prion Disease Pathology Surveilance Center, Case Western Reserve University	Special Government Employee (SGE) Member
Sigurdson, Christina	07/01/2013	06/09/2016	Assoc. Prof., Univ. of Calif. San Diego, LaJolla, CA	Special Government Employee (SGE) Member
Tran, Nga	06/04/2013	06/09/2016	Senior Managing Scientist, Exponent, Washington, DC	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 tabacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Transmissible Spongiform Encephalopathies Advisory Committee supports FDA's mission and strategic action plan by reviewing and evaluating available scientific data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health. The Committee supports FDA's mission by using science-based efficient risk management in all of its activities. The Committee recommendations provide the most health promotion and protection at the least cost for the public. This Committee assists the Agency in ensuring timely, high, quality, cost-effective processes for review of new policies and guidelines, effective communication and working relationships with stakeholders to enhance U.S. and global health outcomes, accurately analyzing risks associated with medical products, facilitating the development and availability of medical countermeasures to limit the effects of a terrorist attack on the civilian and military populations, protecting the safety and security of biologics, including products that may be at risk for transmission of spongiform encephalopathies, all key components of FDA's strategic plan objectives. The committee was terminated on June 9, 2016.

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

NA

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 Transmissible Spongiform Encephalopathies 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 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?

25

Number of Recommendations Comments

The Committee made approximately 25 recommendations from FY2003 through FY2016. See 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

The Agency 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 an investigational 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	☑
Online Agency Web Site	☑
Online Committee Web Site	☐
Online GSA FACA Web Site	☑
Publications	☑
Other	☐

Access Comments

N/A