2018 Current Fiscal Year Report: Blood Products Advisory Committee

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

3. Committee or Subcommittee	3b. GSA Committee No.
Blood Products Advisory Committee	224

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	05/13/2018	05/13/2020	

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 3 **17b. Closed** 0 **17c. Partially Closed** 1 **Other Activities** 0 **17d. Total** 4

Meetings and Dates

Purpose	Start	End
At the November 30, 2017 meeting, in the morning the Committee discussed bacterial risk control strategies for blood collection establishments and transfusion services to enhance the safety and availability of platelets for transfusion. On December 1, 2017, the committee discussed strategies to reduce the risk of transfusion-transmitted Zika virus.	11/30/2017	12/01/2017
On March 22, 2018, the Joint Meeting of the Blood Products Advisory Committee and the Microbiology Devices Panel of the Medical Devices Advisory Committee met in open session to discuss and provide advice regarding the reclassification from Class III to Class II of nucleic acid and serology-based in vitro diagnostic devices indicated for use as aids in diagnosis of hepatitis C virus (HCV) infection and/or for use as aids in the management of HCV infected patients. The devices discussed by the Committee during the meeting are post-amendment devices that currently are classified into Class III under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)).	03/22/2018	03/22/2018

On June 22, 2018, in the morning open session, under Topic 1, the Committee heard presentations on the research programs in the Laboratory of Emerging Pathogens (LEP), Laboratory of bacterial and TSE Agents (LBTSE) and from the Laboratory of Molecular Virology (LMV) in the Division of Emerging Transfusion-Transmitted Diseases (DETTD), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), FDA. After the conclusion of the open session, the meeting was closed to the public from 12:55 p.m. to 1:40 p.m. to permit discussion where disclosure would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C 552b(c)(6). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making decisions regarding pay adjustments of service fellows or promotion and permanent staff regarding individual scientists. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy. In the afternoon, in open session, under Topic II, the Committee heard presentations on the research program in the Hemostasis Branch (HB), in the Division of Plasma Protein Therapeutics (DPPT), Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER), FDA. After the open session, the meeting was closed to the public from 3:45 p.m. to 4:20 p.m. to permit discussion where disclosure would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C 552b(c)(6). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making decisions regarding pay adjustments of service fellows or promotion and permanent staff regarding individual scientists. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.	06/22/2018 - 06/22/2018
On July 18, 2018, the Blood Products Advisory Committee met in open session to discuss and provide advice regarding bacterial risk control strategies for blood collection establishments and transfusion services to enhance the safety and availability of platelets for transfusion. The Committee discussed the available strategies to control the risk of bacterial contamination of platelets with 5-day and 7-day dating, including bacterial testing using culture-based devices and rapid bacterial detection devices and implementation of pathogen reduction technology. On July 19, 2018, the Committee functioned as a medical device panel. The Committee met in open session to discuss and provide advice regarding the device reclassification from Class III to Class II of nucleic acid and serology-based point-of-care and laboratory-based in vitro diagnostic devices indicated for use as aids in the diagnosis of human immunodeficiency virus (HIV) infection. The devices discussed by the Committee during the meeting are post-amendment devices that currently are classified into Class III under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)).	07/18/2018 - 07/19/2018

Number of Committee Meetings Listed: 4

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$30,734.00	$16,952.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$417,708.00	$368,718.00
18a(4). Personnel Pmts to Non-Member Consultants	$4,638.00	$17,499.00
18b(1). Travel and Per Diem to Non-Federal Members	$28,990.00	$15,954.00
18b(2). Travel and Per Diem to Federal Members	$3,222.00	$2,067.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$26,005.00	$19,853.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$132,936.00	$106,579.00
18d. Total	$644,233.00	$547,622.00
19. Federal Staff Support Years (FTE)	2.65	2.30

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates data on the safety and effectiveness of blood products intended for use in the diagnosis, prevention or treatment of human diseases.

On June 22, 2018, the Blood Products Advisory Committee (BPAC) participated in a partially closed meeting in person and in teleconference. In open session, the Committee heard presentations on the research programs in the Laboratory of Emerging Pathogens (LEP), Laboratory of bacterial and TSE Agents (LBTSE) and from the Laboratory of Molecular Virology (LMV) in the Division of Emerging Transfusion-Transmitted Diseases (DETTD), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), FDA. After the conclusion of the open session, the meeting was closed to the public from 12:55 p.m. to 1:40 p.m. to permit discussion where disclosure would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C 552b(c)(6). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making decisions regarding pay adjustments of service fellows or promotion and permanent staff regarding individual scientists. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy. In the afternoon, in open session, under Topic II, the Committee heard presentations on the research program in the Hemostasis Branch (HB), in the Division of Plasma Protein Therapeutics (DPPT), Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER), FDA. After the open session, the meeting was closed to the public from 3:45 p.m. to 4:20 p.m. to permit discussion where disclosure would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C 552b(c)(6). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making decisions regarding pay adjustments of service fellows or promotion and permanent staff regarding individual scientists. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

20b. How does the Committee balance its membership?

The committee consists of experts in clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biotechnology, and other related specialties. One member is technically qualified and identified with consumer interests and one non-voting member represents the point of view of industry.

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

The committee held four meetings and conducted two intramural research site visits in FY 2018. With the increasing concern on issues relative to blood and blood safety and the rapid growth of biotechnology products, it is anticipated that the workload of this committee will be demanding. Six meetings and four intramural site reviews are planned for FY 2019.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the committee are drawn from academia, research, clinical practice, and consumer interests. Their advice and input lends credibility to regulatory decisions made and has representatives of knowledge and experience needed from informed sources. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientists on a full-time basis at maximum rates of compensations.

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

FDA is required to close portions of meetings to permit discussion of personal information that constitutes an unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

21. Remarks

No reports are required from this committee. Waiting for two meeting minutes to be approved by OBRR in order to post on the web and create the minute links for appropriate meetings.

Designated Federal Officer

Bryan Hatfield Emery Center for Biologics Evaluation and Research, FDA

Committee Members	Start	End	Occupation	Member Designation
Baker, Judith	09/29/2017	09/30/2021	CONSUMER REPRESENTATIVE Public Health Director Western States Hemophelia Network	Special Government Employee (SGE) Member
Basavaraju, Sridhar	06/24/2013	09/30/2022	Centers for Disease Control, Epidemiology/ Infectious Disease	Regular Government Employee (RGE) Member
Chitlur, Meera	01/19/2016	09/30/2019	Associate Professor of Pediatrics, Wayne State University, Children's Hospital of Michigan, Expert in Hematology and Oncology	Special Government Employee (SGE) Member
DeMaria, Alfred	01/18/2017	09/30/2020	Medical Director, State Epedemiologist Bureau of Infectious Disease and Laboratory Institute	Special Government Employee (SGE) Member
DeVan, Michael	01/18/2017	09/30/2020	Medical Director, Blood Services Pathologist Walter Reed National Military Medical Center	Regular Government Employee (RGE) Member
Escobar, Miquel	08/26/2016	09/30/2020	Professor, University of Texas Health Science Center at Houston	Special Government Employee (SGE) Member
Kaufman, Richard	06/21/2018	09/30/2022	Brigham and Women's Hospital, Boston MA, Transfusion Medicine	Special Government Employee (SGE) Member
Kindzelski, Andrei	06/21/2018	09/30/2022	Hematologist	Regular Government Employee (RGE) Member
Leitman, Susan	10/01/2017	09/30/2018	Transfusion Medicine expert, Retired Chief, Department of Transfusion Medicine, National Institutes of Health	Special Government Employee (SGE) Member

Lewis, Roger	09/29/2017	09/30/2021	Biostatistitian, Harbor UCLA Medical Center	Special Government Employee (SGE) Member
Ortel, Thomas	06/17/2016	09/30/2020	Chief, Division of Hematology, Duke University Medical Center	Special Government Employee (SGE) Member
Rees, Robert	01/19/2016	09/30/2019	Manager, Blood Bank Licensing and Regulatory Compliance regulator	Special Government Employee (SGE) Member
Sandberg, Sonja	10/30/2014	09/30/2018	Applied Mathmatics expert, Professor Mathematics, Framingham State University	Special Government Employee (SGE) Member
Schreiber, Martin	06/21/2018	09/30/2022	Trauma Surgeon	Special Government Employee (SGE) Member
Shapiro, Any	06/21/2018	09/30/2022	Internal Medicine/ Hematology	Special Government Employee (SGE) Member
Stapleton, Jack	01/18/2017	09/30/2020	Staff Physician, Iowa City VA Medical Center	Regular Government Employee (RGE) Member
Stramer, Susan	07/28/2017	09/30/2020	Vice President of Scientific Affairs, American Red Cross	Representative Member
Sullivan, Kathleen	01/18/2017	09/30/2020	Pediatric Rheumatology	Special Government Employee (SGE) Member

Number of Committee Members Listed: 18

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 Blood Product Advisory Committee supports FDA's mission and strategic action plan by reviewing and evaluating data on the safety and effectiveness of blood products intended for use in the diagnosis, prevention or treatment of human diseases. The Committee also considers the quality and relevance of FDA's research program which, provides scientific support for the regulation of these products. The Committee supports FDA's mission by using science-based 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 technologies/pre-market submissions, 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 (vaccines, blood, and blood products) all key components of FDA's strategic plan objectives.

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 Blood Products 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?
112

Number of Recommendations Comments
The Committee made 112 recommendations from FY2003 through FY2018. 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?
79%

% 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