2018 Current Fiscal Year Report: Device Good Manufacturing Practice 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.
Device Good Manufacturing Practice Advisory Committee	841

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	05/17/1987		

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 Statutory (Congress Created)

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 360c-j	05/28/1976	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 0 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 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	$60,718.00	$58,321.00
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.)	$15,180.00	$14,580.00
18d. Total	$75,898.00	$72,901.00

19. Federal Staff Support Years (FTE)	0.40	0.40

20a. How does the Committee accomplish its purpose?
The Device Good Manufacturing Practice Advisory Committee reviews proposed requirements for good manufacturing practices (GMPs) governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices. The committee reviews and provides recommendations on proposed GMP regulations and on petitions for exemption from GMP's regulations.

20b. How does the Committee balance its membership?
By law, the composition of this committee is: three government representatives (local, state and federal); two health professionals; two industry representatives; and two representatives from the general public.

20c. How frequent and relevant are the Committee Meetings?
The committee meets approximately once a year or as required. In FY 2018 there were no issues necessary to be brought before the committee.

20d. Why can't the advice or information this committee provides be obtained elsewhere?
This statutory committee is required under the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act.

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

21. Remarks
Although this committee did not meet in FY 2018, time was devoted to reappointing current 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.

Designated Federal Officer
Aden S. Asefa Health Science Policy Analyst, Center for Devices and Radiological Health/FDA

Committee Members	Start	End	Occupation	Member Designation

Asmail, Clara	12/11/2017	05/31/2021	Government Representative: Sr. Program Advisor, Dept of Energy, Washington, DC	Regular Government Employee (RGE) Member
Cranmer, David	09/11/2015	05/31/2019	Government Representative; Sr. Account Manager, National Inst. of Standards & Tech., Gaithersburg, MD	Regular Government Employee (RGE) Member
David, Yadin	12/10/2014	05/31/2018	General Public Representative: Principal, Biomedical Eng. Consultants, LLC, Houston, TX	Special Government Employee (SGE) Member
Dimmick, Lisa	04/24/2018	05/31/2021	Government Representative: Team Leader, Medical Radiation Safety Team, U.S. Nuclear Regulatory Commission, North Bethesda, MD	Regular Government Employee (RGE) Member
Eicholtz, Martin	12/11/2017	05/31/2021	General Public Representative: Dir., GMP Operations, Nationwide Children's Hospital	Special Government Employee (SGE) Member
Phillips, Robert	04/24/2018	05/31/2021	Vice President, Quality and Regulatory, North America, Siemens Healthcare, Malvern, PA	Representative Member
Troupe (Lott), Michelle	04/26/2016	05/31/2019	Principle & Founder, Lean RAQA Systems, LLC., Marana, AZ	Representative Member

Number of Committee Members Listed: 7

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 Device Good Manufacturing Practice Advisory Committee supports FDA's mission and strategic action plan by reviewing proposed regulations and guidance documents intended to ensure the safety and effectiveness of medical devices and making recommendations to the Agency.

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 Device Good Manufacturnig Practice 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?
1

Number of Recommendations Comments
The Committee made 1 recommendation from FY 03 through FY 18. See question 20a of the annual report or specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
0%

% 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?

0%

% 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

Feedback are provided in an indirect way. For example, with the regulation that was promulgated in 1996, the fact that the regulation was determined acceptable by the Agency and became law is a form of feedback. Also with the process validation guidance document, the document would not have been finalized without the support of various components, e.g., FDA's Office of the Chief Counsel.

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

NA

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