

2024 Current Fiscal Year Report: Device Good Manufacturing Practice Advisory Committee

Report Run Date: 04/26/2024 08:33:34 PM

1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2024

3. Committee or Subcommittee

Device Good Manufacturing Practice
Advisory Committee

3b. GSA

Committee No.

841

4. Is this New Fiscal Year?

No

5. Current Charter

05/17/1987

6. Expected Renewal Date

7. Expected Term Date

8a. Was Terminated During Fiscal Year?

No

8b. Specific Termination Authority

8c. Actual Term Date

9. Agency

Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

Not Applicable

10b.

Legislation Pending?

Not Applicable

11. Establishment Authority

Statutory (Congress Created)

12. Specific Establishment Authority

21 U.S.C. 360c-j

13. Effective Date

05/28/1976

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee

Scientific Technical Program
Advisory Board

16a. Total

Number of Reports

No Reports for
this Fiscal Year

17a.

Open

0

17b. Closed

0

17c. Partially Closed

0

Other Activities

0

Meetings and Dates

No Meetings

Current Next

FY

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 | \$0.00 | \$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.) | \$0.00 | \$0.00 |
| 18d. Total | \$0.00 | \$0.00 |
| 19. Federal Staff Support Years (FTE) | 0.00 | 0.00 |

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 2023 no meeting was held and none is planned for the coming year.

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 2023, considerable time was devoted to reviewing applications for new nominees, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was also 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, providing ethics training and also reviewing financial disclosures for potential committee members. Alisha R. Loy resigned 2/7/2023. The Agency will continue to publish request for nominations in the Federal Register Notices to receive nominations to fill current and up-coming vacancies.

Designated Federal Officer

Jarrold Collier Public Health Analyst, Center for
Devices and Radiological Health/FDA

| Committee Members | Start | End | Occupation | Member Designation |
|------------------------------|------------|------------|--|--|
| Culbertson, Jeri | 12/08/2021 | 05/31/2025 | Infection Prevention Consultant | Special Government Employee (SGE) Member |
| David, Yadin | 01/11/2022 | 05/31/2025 | Principal, Biomedical Engineering Consultants, LLC | Special Government Employee (SGE) Member |
| Dimmick, Lisa | 04/24/2018 | 05/31/2026 | Team Leader, Medical Radiation Team, U.S. Nuclear Regulatory Commission | Regular Government Employee (RGE) Member |
| Gillerman, Gordon | 12/08/2021 | 05/31/2024 | Director, Standards Coordination Office, National Institute of Standards and Technology Director, Regulatory Consulting Center, Assistant Professor, Department of Regulatory and Quality Sciences, School of Pharmacy, University of Southern California | Regular Government Employee (RGE) Member |
| Kuo, Chiaoyun (Benson) | 01/11/2022 | 05/31/2026 | Standards Executive, Environmental Protection Specialist, U.S. Environmental Protection Agency Vice President, Quality and Technology, North America, Siemens Healthineers | Special Government Employee (SGE) Member |
| Owen, Elise | 01/11/2022 | 05/31/2024 | | Regular Government Employee (RGE) Member |
| Phillips, Robert | 04/24/2018 | 05/31/2025 | | Representative Member |

| | | | |
|-----------|------------|------------|---------------------------|
| | | | Intl. Regulatory |
| | | | Affairs and Quality |
| Sardeson, | 07/30/2020 | 05/31/2024 | Compliance Representative |
| Scott | | | Leader, 3M Health Member |
| | | | Care Business, St. |
| | | | Paul, MN |

Number of Committee Members Listed: 8

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 | <input checked="" type="checkbox"/> |
| Trust in government | <input checked="" type="checkbox"/> |
| Major policy changes | <input checked="" type="checkbox"/> |
| Advance in scientific research | <input checked="" type="checkbox"/> |
| Effective grant making | <input type="checkbox"/> |
| Improved service delivery | <input type="checkbox"/> |
| Increased customer satisfaction | <input checked="" type="checkbox"/> |
| Implementation of laws or regulatory requirements | <input checked="" type="checkbox"/> |
| Other | <input type="checkbox"/> |

Outcome Comments

NA

What are the cost savings associated with this committee?

Checked if Applies

| | |
|----------------------------|-------------------------------------|
| None | <input type="checkbox"/> |
| Unable to Determine | <input checked="" type="checkbox"/> |
| Under \$100,000 | <input type="checkbox"/> |
| \$100,000 - \$500,000 | <input type="checkbox"/> |
| \$500,001 - \$1,000,000 | <input type="checkbox"/> |
| \$1,000,001 - \$5,000,000 | <input type="checkbox"/> |
| \$5,000,001 - \$10,000,000 | <input type="checkbox"/> |
| Over \$10,000,000 | <input type="checkbox"/> |
| Cost Savings Other | <input type="checkbox"/> |

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?

2

Number of Recommendations Comments

The Committee made 2 recommendation from FY 03 through FY 23.

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

75%

% 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. This number represents an approximation of the percentage of recommendations that the agency has fully implemented or plans to fully implement.

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 is 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 | <input checked="" type="checkbox"/> |
| Reallocated resources | <input type="checkbox"/> |
| Issued new regulation | <input checked="" type="checkbox"/> |
| Proposed legislation | <input type="checkbox"/> |
| Approved grants or other payments | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

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 | <input checked="" type="checkbox"/> |
| Online Agency Web Site | <input checked="" type="checkbox"/> |
| Online Committee Web Site | <input checked="" type="checkbox"/> |
| Online GSA FACA Web Site | <input checked="" type="checkbox"/> |
| Publications | <input checked="" type="checkbox"/> |
| Other | <input type="checkbox"/> |

Access Comments

N/A