# 2020 Current Fiscal Year Report: Nonprescription Drugs Advisory Committee

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| 1. Department or Agency | 2. Fiscal Year |
|---|---|
| Department of Health and Human Services | 2020 |
| **3. Committee or Subcommittee** | **3b. GSA Committee No.** |
| Nonprescription Drugs Advisory Committee | 984 |

| 4. Is this New During Fiscal Year? | 5. Current Charter | 6. Expected Renewal Date | 7. Expected Term Date |
|---|---|---|---|
| No | 08/27/2019 | 08/27/2021 | |

| 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** 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 | $5,500.00 |
| **18a(2). Personnel Pmts to Federal Members** | $0.00 | $550.00 |
| **18a(3). Personnel Pmts to Federal Staff** | $174,365.00 | $177,227.00 |
| **18a(4). Personnel Pmts to Non-Member Consultants** | $0.00 | $3,850.00 |
| **18b(1). Travel and Per Diem to Non-Federal Members** | $0.00 | $7,617.00 |
| **18b(2). Travel and Per Diem to Federal Members** | $0.00 | $762.00 |
| **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 | $3,195.00 |
| **18c. Other(rents,user charges, graphics, printing, mail, etc.)** | $43,591.00 | $47,295.00 |
| **18d. Total** | $217,956.00 | $245,996.00 |

| | | |
|---|---|---|
| **19. Federal Staff Support Years (FTE)** | 1.10 | 1.10 |

**20a. How does the Committee accomplish its purpose?**

The Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

**20b. How does the Committee balance its membership?**

Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

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

The Committee did not meet during FY-20. It is expected that the Committee will meet approximately one to two times during FY-21.

**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 FDA regulatory decisions. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientist on a full-time basis at a maximum rate of compensation.

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

The Committee held no closed meetings during FY-20.

## 21. Remarks

Although this Committee did not meet in FY-20, considerable time was devoted to appointing 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. Please note that advisory committees meetings are planned and convened based on the needs of the FDA. Although the current charter states that the Committee will hold meetings approximately 4 times a year, this is only an estimation based on data from previous years and will be revised at the next Charter Renewal, if needed.

## Designated Federal Officer

Moon Hee Veronica Choi DFO

| Committee Members | Start | End | Occupation | Member Designation |
|---|---|---|---|---|
| Baron, Elma | 06/01/2016 | 05/31/2024 | Professor of Dermatology, Case Western Reserve University School of Medicine | Regular Government Employee (RGE) Member |
| Dato, Mark | 11/01/2019 | 10/31/2023 | Retired: Director, Global Technology, Procter and Gamble Healthcare | Representative Member |
| Di Francesco, Lorenzo | 06/01/2017 | 05/31/2021 | Professor of Medicine, Division of General Internal Medicine & Geriatrics, Emory University School of Medicine | Special Government Employee (SGE) Member |
| Farber, Neil | 06/01/2016 | 05/31/2020 | Professor of Clinical Medicine, University of California, San Diego | Special Government Employee (SGE) Member |
| King, Tonya | 06/01/2016 | 05/31/2024 | Professor of Biostatistics, Department of Public Health Sciences, Pennsylvania State University College of Medicine | Special Government Employee (SGE) Member |
| Krinsky, Daniel | 04/24/2019 | 05/31/2022 | Professor, Department of Pharmacy Practice at Northeast Ohio Medical University | Special Government Employee (SGE) Member |
| Mack-Brooks, Pamel | 04/04/2018 | 05/31/2022 | CONSUMER REPRESENTATIVE; Nursing Instructor, Rowan College at Burlington County | Special Government Employee (SGE) Member |
| Neill, Richard | 06/01/2017 | 05/31/2021 | Associate Professor of Clinical Family Medicine and Community Health (Retired), Barraud Street Health Center, Tararua Health Group, New Zealand | Special Government Employee (SGE) Member |
| Parker, Ruth | 06/01/2020 | 05/31/2024 | Professor of Medicine, Pediatrics, and Public Health | Special Government Employee (SGE) Member |
| Pisarik, Paul | 06/01/2020 | 05/31/2024 | Urgent Care Physician, Warren Clinic Tulsa Hills Urgent Care | Special Government Employee (SGE) Member |
| Pruchnicki, Maria | 06/01/2019 | 05/31/2023 | Associate Professor of Clinical Pharmacy, Ohio State University College of Pharmacy | Special Government Employee (SGE) Member |

| | | | | |
|---|---|---|---|---|
| Roumie, Christianne | 06/01/2019 | 05/31/2022 | Associate Professor, Internal Medicine and Pediatrics, Vanderbilt University, VA Tennessee Valley Healthcare | Regular Government Employee (RGE) Member |
| Wu, Victor | 06/01/2016 | 05/31/2020 | Chief Medical Officer, Tennessee Division of Health Care Finance and Administration | Special Government Employee (SGE) Member |

**Number of Committee Members Listed:** 13

**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 Nonprescription Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner of Food and Drugs either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee will serve as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA’s mission and regulatory responsibilities. This support 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 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 Non-Prescription 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?**
18

**Number of Recommendations Comments**
The Committee made 18 recommendations from FY-03 through FY-20.

**What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?**
84%

**% 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, 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?**
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**
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