2024 Current Fiscal Year Report: Medical Imaging Drugs Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2024

3. Committee or Subcommittee	3b. GSA Committee No.
Medical Imaging Drugs Advisory Committee	917

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	05/18/2023	05/18/2025	

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	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	$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 Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are authorities in the fields of nuclear

medicine, radiology, epidemiology or statistics, and related specialties. The committee includes one technically qualified voting member who is identified with consumer interests. 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 met once in FY-23. On August 1, 2023, the Medical Imaging Drugs Advisory Committee discussed dosimetry data needed to support the initial clinical study in an original investigational new drug (IND) application for certain new positron emission tomography (PET) drugs. FDA obtained the committee's input on the following: (1) the sufficiency of available data from animal or human studies involving certain positron emitting radionuclides (e.g., C11, F18) to allow a reasonable calculation of radiation-absorbed dose to the whole body and critical organs upon administration of a new PET drug containing certain radionuclides to a human subject in first-in-human studies; and (2) the reasonableness of a proposed list of numerical radioactivity thresholds for new PET drugs containing these radionuclides, such that Phase 1 studies that will both (a) administer sub-threshold activities and (b) obtain sufficient human data for dosimetry calculations may be found safe-to-proceed in the absence of dosimetry data based on prior animal administration of the new PET drug under investigation. Agency Action: The Agency is still reviewing the recommendations made at this meeting. It is expected that the Committee will meet one to two times during FY-24.

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-23.

21. Remarks

David Andrews resigned as a MIDAC committee member on January 24, 2022.

Designated Federal Officer

Yvette Waples Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Bolch, Wesley	09/28/2016	06/30/2024	Director, Advanced Laboratory for Radiation Dosimetry Studies, University of Florida	Special Government Employee (SGE) Member
Hackney, David	09/28/2016	06/30/2024	Chief of Neuroradiology, Beth Israel Deaconess Medical Center	Special Government Employee (SGE) Member
Herscovitch, Peter	07/30/2015	06/30/2025	Department Director, PET Department, National Institutes of Health	Regular Government Employee (RGE) Member
Jacobs, Paula	09/28/2016	06/30/2024	Expert Advisor, Division of Cancer Treatment and Diagnosis, National Cancer Institute	Regular Government Employee (RGE) Member
Mintun, Mark	11/01/2019	10/31/2023	Vice President of Pain and Neurodegeneration, Research and Development, Avid Radiopharmaceuticals	Representative Member

Oates, Mary Elizabeth	07/01/2020	06/30/2024	Professor of Radiology and Medicine, University of Kentucky	Special Government Employee (SGE) Member
Rosenthal, Eben	07/01/2021	06/30/2025	Professor and Chair, Department of Otolaryngology, Vanderbilt University Medical Center	Special Government Employee (SGE) Member
Sanghani, Rupa	07/01/2021	06/30/2025	Director of Nuclear Cardiology, Rush University Medical Center	Special Government Employee (SGE) Member

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 Medical Imaging Drugs Advisory Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology and makes appropriate recommendations to the Commissioner of Food and Drugs. This supports 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 Medical Imaging 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?

5

Number of Recommendations Comments

The Committee made 5 recommendations from FY-03 through the FY-23.

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
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. Please see https://www.fda.gov/.

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 a new medical product.

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

NA