2024 Current Fiscal Year Report: Obstetrics, Reproductive and Urologic Drugs Advisory Committee

Report Run Date: 05/01/2024 10:08:49 PM

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

3. Committee or Subcommittee	3b. GSA Committee No.
Obstetrics, Reproductive and Urologic Drugs Advisory Committee	871

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	03/23/2022	03/23/2024	

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 on the safety and effectiveness of marketed and investigational human drug products for use in the practice of obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in obstetrics, gynecology, urology, pediatrics, epidemiology, or statistics, and

related specialties. The Committee also will include one technically qualified member who is identified with consumer interests and may include one non-voting representative who is identified with industry interests.

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

In FY-23, the Committee held one meeting. At this meeting , the Committee, met in joint session with other Committees but was not the lead Committee. See the Agency Recommendations, Remarks section for a list of joint meetings in which the Committee was not the lead Committee. On May 9-10, 2023, a joint meeting was held between the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive, and Urologic Drugs Advisory Committee It is expected that the Committee will meet 1-3 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

There were no reports required for this Committee in FY-23. In FY-23, the Committee held one

meeting. At one meeting, the Committee, met in joint session with other committees but was not the lead Committee. So that joint meetings are not counted twice in the FACA database, they will be reported under the primary or lead Committee. For the purposes of this database, the secondary Committee still reports meeting information and costs associated under this section of the report as well as the cost section. On May 9-10, 2023, the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee met to discuss supplemental new drug application (sNDA) 017031/S-041, for OPILL (norgestrel) Tablet, 0.075 mg, submitted by Laboratoire HRA Pharma. OPILL was proposed for nonprescription use as a once daily oral contraceptive to prevent pregnancy. The members unanimously (17 to 0) agreed that there was adequate information to conclude that the majority of consumers will be likely to use norgestrel tablet properly, such that the benefits of making this available for nonprescription use exceed the risks. Agency Action: On July 13, 2023, the Agency approved Opill (norgestrel) tablet for nonprescription use to prevent pregnancy— the first daily oral contraceptive approved for use in the U.S. without a prescription. Approval of this progestin-only oral contraceptive pill provides an option for consumers to purchase oral contraceptive medicine without a prescription at drug stores, convenience stores and grocery stores, as well as online.

Designated Federal Officer

Joyce Frimpong Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation

Alukal, Joseph	07/01/2022	06/30/2026	Associate Professor, Department of Urology, Columbia University Irving Medical Center	Special Government Employee (SGE) Member
Anger, Jennifer	08/15/2022	06/30/2026	Professor of Urology and Vice Chair of Research, UC San Diego Department of Urology	Special Government Employee (SGE) Member
Eisenberg, Esther	02/22/2021	06/30/2024	Program Director, Reproductive Medicine and Infertility Program, National Institutes of Health	Regular Government Employee (RGE) Member
Fox, Michelle	11/01/2019	10/31/2023	Section Head, Women's Health Global Clinical Development Merck Research Laboratories	Representative Member
Gass, Margery	07/28/2017	06/30/2024	Professor of Clinical Emerita, University of Cincinnati College of Medicine	Special Government Employee (SGE) Member
Li, Tianjing	12/28/2021	06/30/2025	Associate Professor, University of Colorado Anschutz Medical Campus	Special Government Employee (SGE) Member
Lindsay, Michael	02/22/2021	06/30/2024	Luella Klein Professor, Division of Maternal-Fetal Medicine, Emory University School of Medicine	Special Government Employee (SGE) Member
Munn, Mary	12/28/2021	06/30/2025	Professor and Chairman, The University of South Alabama Children's and Women's Hospital	Special Government Employee (SGE) Member
Shaw, Pamela	07/28/2017	06/30/2025	Senior Investigator, Kaiser Permanente Washington Health Research Institute	Special Government Employee (SGE) Member
Shields, Kristine	02/22/2021	06/30/2024	CONSUMER REP, Shields' Medical Writing & Consulting, LLC	Special Government Employee (SGE) Member

Number of Committee Members Listed: 10

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 Advisory Committee for Reproductive Health Drugs supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of marketed and investgational human drug products for use in the practice of obstetrics, gynecology, and related specialties, 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

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 Obstetrics, Reproductive and Urologic 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?

34

Number of Recommendations Comments

The Committee made 34 recommendations 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?

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

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

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