2023 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	2023

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	08/27/2023	08/27/2025	

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
3	0	0	0	3

Meetings and Dates

Purpose	Start	End

The Nonprescription Drugs Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee discussed supplemental new drug application 208411/S–006, for NARCAN (naloxone hydrochloride) nasal spray, 4 mg/0.1 mL, submitted by Emergent BioSolutions Inc. NARCAN is proposed for nonprescription treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. The issues for discussion was on the adequacy of the data supporting the nonprescription application. This product represented a potential first in class product in a new therapeutic category for nonprescription drugs.	02/15/2023 - 02/15/2023
The Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee met jointly 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.	05/09/2023 - 05/10/2023
The committee discussed new data regarding the 'Generally Recognized as Safe and Effective' (GRASE) status of oral phenylephrine as a nasal decongestant that have become available since FDA last examined the issue.	09/11/2023 - 09/12/2023

Number of Committee Meetings Listed: 3

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$41,819.00	$13,509.00
18a(2). Personnel Pmts to Federal Members	$5,890.00	$1,228.00
18a(3). Personnel Pmts to Federal Staff	$190,803.00	$199,862.00
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.)	$80,220.00	$66,388.00
18d. Total	$318,732.00	$280,987.00
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?

In FY-23, the Committee held 3 meetings. On February 15, 2023, the Nonprescription Drugs Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee met jointly to discuss supplemental new drug application 208411/S–006, for NARCAN (naloxone hydrochloride) nasal spray, 4 mg/0.1 mL, submitted by Emergent BioSolutions Inc. NARCAN is proposed for nonprescription treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. The issues for discussion was on the adequacy of the data supporting the nonprescription application. This product represents a potential first in class product in a new therapeutic category for nonprescription drugs. The members unanimously (19 to 0) agreed that the benefit profile of Narcan Nasal Spray was supportive of its use as a nonprescription opioid overdose reversal agent.

Agency Action: On March 29, 2023, the Agency approved Narcan, 4 milligram (mg) naloxone hydrochloride nasal spray for over-the-counter (OTC), nonprescription, use – the first naloxone product approved for use without a prescription. Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose. 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. On September 11-12, 2023, the Nonprescription Drugs Advisory Committee discussed new data regarding the ‘Generally Recognized as Safe and Effective’ (GRASE) status of oral phenylephrine as a nasal decongestant that have become available since FDA last examined the issue. The Committee members were unanimously in agreement (16 to

0) that the current scientific data do not support that the monograph dosage of orally administered phenylephrine is effective as a nasal decongestant. Agency Action: The Agency is still reviewing recommendations made at the meeting. It is expected that the Committee will meet 1 time 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.

Designated Federal Officer
Moon Choi Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Amirshahi, Maryann	09/11/2023	09/12/2023	Professor of Emergency Medicine, Georgetown University School of Medicine, Associate Medical Director, National Capital Poison Center	Special Government Employee (SGE) Member
Armstrong, Deborah	05/09/2023	05/10/2023	Professor of Oncology Professor of Gynecology and Obstetrics Johns Hopkins Kimmel Cancer Center	Special Government Employee (SGE) Member

Ballou, Jordan	02/15/2023	02/15/2023	Clinical Associate Professor Kennedy Pharmacy Innovation Center University of South Carolina College of Pharmacy	Special Government Employee (SGE) Member
Baron, Elma	06/01/2016	05/31/2024	Professor of Dermatology Case Western Reserve University School of Medicine	Regular Government Employee (RGE) Member
Baur, Cynthia	05/09/2023	05/10/2023	Director, Horowitz Center for Health Literacy Horowitz Endowed Chair in Health Literacy University of Maryland (UMD) School of Public Health	Special Government Employee (SGE) Member
Berenson, Abbey	05/09/2023	05/10/2023	Professor, Departments of Ob/Gyn and Pediatrics Director Center for Interdisciplinary Research in Women's Health University of Texas Medical Branch	Special Government Employee (SGE) Member
Berlan, Elise	05/09/2023	05/10/2023	Professor of Clinical Pediatrics The Ohio State University College of Medicine Faculty Physician Division of Adolescent Medicine Nationwide Children’s Hospital	Special Government Employee (SGE) Member
Blalock, Susan	09/11/2023	09/12/2023	Professor Emeritus, University of North Carolina at Chapel Hill Eshelman School of Pharmacy	Special Government Employee (SGE) Member
Brent, Jeffrey	02/15/2023	02/15/2023	Distinguished Clinical Professor of Medicine and Emergency Medicine University of Colorado School of Medicine	Special Government Employee (SGE) Member
Brittain, Kristy	06/01/2023	05/31/2027	Professor, Medical University of South Carolina College of Pharmacy	Special Government Employee (SGE) Member
Calis, Karim	09/11/2023	09/12/2023	Senior Scientist,Director of Clinical Research and Compliance, Division of Intramural Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Hatfield Clinical Research Center	Regular Government Employee (RGE) Member

Catlin, Jesse	05/09/2023	05/10/2023	Professor of Marketing College of Business California State University, Sacramento	Special Government Employee (SGE) Member
Clement, Stephen	06/01/2021	05/31/2025	Associate Professor of Medical Education, University of Virginia School of Medicine; Practicing Physician, INOVA Fairfax Hospital	Special Government Employee (SGE) Member
Coykendall, Elizabeth	02/15/2023	02/15/2023	Emergency Medicine, Paramedic, MHA Candidate Urgent Care Quality, Safety, and Education Lead PM Pediatric Care	Special Government Employee (SGE) Member
Coyle, Maria	06/01/2019	05/31/2023	Associate Clinical Professor, The Ohio State University College of Pharmacy	Special Government Employee (SGE) Member
Curtis, Kathryn	05/09/2023	05/10/2023	Health Scientist, Division of Reproductive Health Centers for Disease Control and Prevention	Regular Government Employee (RGE) Member
D'Agostino, Emma	09/11/2023	09/12/2023	Consultant, Cystic Fibrosis Foundation; Lead Medical Writer, BOLDSCIENCE	Special Government Employee (SGE) Member
Dato, Mark	11/01/2019	10/31/2023	Retired: Director, Global Technology, Procter and Gamble Healthcare	Representative Member
Dykewicz, Mark	09/11/2023	09/12/2023	Raymond and Alberta Slavin Endowed Professor in Allergy and Immunology, Saint Louis University School of Medicine	Special Government Employee (SGE) Member
Espey, Eve	05/09/2023	05/10/2023	Distinguished Professor and Chair Department of Obstetrics and Gynecology University of New Mexico	Special Government Employee (SGE) Member
Everhart, Sabrina	05/09/2023	05/10/2023	Patient Representative	Special Government Employee (SGE) Member
Figg, William	09/11/2023	09/12/2023	Senior Investigator, Associate Director, Center for Cancer Research Acting Chief, Genitourinary Malignancies Branch Chief, Clinical Pharmacology Program National Cancer Institute, National Institutes of Health	Regular Government Employee (RGE) Member

Ginsburg, Diane	06/01/2022	05/31/2026	Clinical Professor, Pharmacy Practice Division; Associate Dean for Healthcare Partnerships The University of Texas at Austin, College of Pharmacy	Special Government Employee (SGE) Member
Haun, Jolie	05/09/2023	05/10/2023	Supervisory Research Health Scientist, Research Service James A. Haley Veterans' Hospital Veterans' Health Administration Adjunct Associate Professor Division of Epidemiology Department of Internal Medicine University of Utah	Regular Government Employee (RGE) Member
Jones, Bridgette	09/11/2023	09/12/2023	Professor of Pediatrics, Divisions of Allergy/Asthma/Immunology and Pediatric Clinical Pharmacology, Toxicology, and Therapeutic Innovation, Children's Mercy Hospitals and Clinics	Special Government Employee (SGE) Member
Kim, Esther	09/11/2023	09/12/2023	Assistant Professor, Otolaryngology/Head Neck Surgery Uniformed Services University of the Health Sciences Chief, Otolaryngology/Head Neck Department	Regular Government Employee (RGE) Member
King, Tonya	06/01/2016	05/31/2024	Professor of Biostatistics, Department of Public Health Sciences The Pennsylvania State University College of Medicine	Special Government Employee (SGE) Member
Le, Jennifer	09/11/2023	09/12/2023	Professor of Clinical Pharmacy University of California San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences	Special Government Employee (SGE) Member
Parker, Ruth	06/01/2020	05/31/2024	Professor Emerita of Medicine Sr. Fellow, Center for Ethics Emory University	Special Government Employee (SGE) Member
Pisarik, Paul	06/01/2020	05/31/2024	Geriatric Physician Archwell Health	Special Government Employee (SGE) Member
Robotti, Suzanne	05/09/2023	05/10/2023	CONSUMER REP President MedShadow Foundation Executive Director DES Action USA	Special Government Employee (SGE) Member

Roth, Katalin	06/01/2021	05/31/2025	Professor of Medicine, Division of Geriatrics and Palliative Medicine, Medical Faculty Associates The George Washington University School of Medicine and Health Sciences	Special Government Employee (SGE) Member
Schwartzott, Jennifer	09/11/2023	09/12/2023	Patient Representative	Special Government Employee (SGE) Member
Walker-Harding, Leslie	06/01/2022	05/31/2026	Ford/Morgan Endowed Professor & Chair, Department of Pediatrics, Associate Dean, University of Washington; Chief Academic Officer & Senior Vice President, Seattle Children’s Hospital	Special Government Employee (SGE) Member

Number of Committee Members Listed: 34

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?
20

Number of Recommendations Comments
The Committee made 20 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

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