2022 Current Fiscal Year Report: Pharmacy Compounding Advisory Committee

Report Run Date: 02/07/2023 12:48:27 AM

1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2022

3. Committee or Subcommittee	3b. GSA Committee No.
Pharmacy Compounding Advisory Committee	5220

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	04/25/2022	04/25/2024	

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 Statutory (Congress Created)

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 353a	11/21/1998	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
1	0	0	0	1

Meetings and Dates

Purpose	Start	End

The committee discussed the following four bulk drug substances nominated for inclusion on the 503A Bulks List: Ammonium tetrathiomolybdate, enclomiphene citrate, ferric subsulfate, and glutathione. The chart below identifies the use(s) FDA reviewed for each of the four bulk drug substances being discussed at this advisory committee meeting. The nominators of these substances or another interested party were invited to make a short presentation supporting the nomination. The committee also discussed revisions FDA is considering to the Withdrawn or Removed List. FDA now is considering whether to amend the rule to add one more entry to the list: Lorcaserin Hydrochloride: All drug products containing lorcaserin hydrochloride. As previously explained in the Federal Register of July 2, 2014 (79 FR 37687 at 37689 through 37690), the list may specify that a drug may not be compounded in any form, or, alternatively, may expressly exclude a particular formulation, indication, dosage form, or route of administration from an entry on the list. Moreover, a drug may be listed only with regard to certain formulations, indications, routes of administration, or dosage forms because it has been found to be unsafe or not effective in those particular formulations, indications, routes of administration, or dosage forms. FDA sought the committee's advice concerning the inclusion of this drug on the list.	06/08/2022 - 06/08/2022	

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$12,386.00	$11,189.00
18a(2). Personnel Pmts to Federal Members	$0.00	$589.00
18a(3). Personnel Pmts to Federal Staff	$182,810.00	$191,622.00
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.)	$51,932.00	$54,199.00
18d. Total	$247,128.00	$257,599.00
19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?

The Committee provides advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are authorities in the fields of pharmacy compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. The core of voting members may include one or more technically qualified members, selected by the Commissioner or designee, who are identified with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee

may include one or more non-voting member(s) who are identified with industry interests.

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

In FY-22, the Committee held one meeting. On June 8, 2022, the Committee discussed the following four bulk drug substances nominated for inclusion on the list of bulk drug substances that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drugs (503A Bulks List): ammonium tetrathiomolybdate (ATTM), enclomiphene citrate, ferric subsulfate, and glutathione. The committee also discussed revisions FDA is considering to the list of drugs that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (Withdrawn or Removed List). FDA now is considering whether to amend the rule to add one more entry to the list: Lorcaserin Hydrochloride: All drug products containing lorcaserin hydrochloride. In the session regarding enclomiphene, the majority of the members (4 Yeses to 8 Noes) voted against placing enclomiphene citrate on the 503A Bulks List. In the session regarding glutathione, the majority of committee members (8 Yeses, 5 Noes, 1 abstention) voted in favor of adding glutathione to the 503A Bulks List. In the session regarding ATTM, the majority of the members (2 Yeses to 13 Noes) voted against placing ATTM on the 503A Bulks List. In the session regarding ferric subsulfate, the Committee (13 members)

unanimously agreed that ferric subsulfate solid or powder should not be included on the 503A Bulks List. In the final session regarding lorcaserin hydrochloride, the Committee (10 members) unanimously agreed that lorcaserin hydrochloride: All drug products containing “lorcaserin hydrochloride” be added to the Withdrawn or Removed List for reasons of safety concerns noted in the presentations. Agency Action: The Agency is reviewing recommendations made at the meeting. It is expected that the committee will meet 1 to 2 times during FY-23.

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 scientists 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 in FY-22.

21. Remarks

There were no reports required for this Committee in FY-22.

Designated Federal Officer

Takyiah Stevenson Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Assis, David	06/08/2022	06/08/2022	Associate Professor of Medicine, Digestive Diseases, Yale School of Medicine	Special Government Employee (SGE) Member

Bassani, Gus	11/01/2019	10/31/2023	Chief Scientific Officer, Professional Compounding Centers of America, Inc.	Representative Member
Bogner, Robin	12/18/2020	09/30/2024	Professor, University of Connecticut School of Pharmacy	Special Government Employee (SGE) Member
Bui, Michael	11/01/2019	10/31/2023	Senior Vice-President, Global Regulatory Affairs, Pyxis Oncology	Representative Member
Calhoun, William	06/08/2022	06/08/2022	Professor and Vice Chair for Research Divisions of Pulmonary/Critical Care, and Allergy/Immunology, University of Texas Medical Branch	Special Government Employee (SGE) Member
Caviness, John	06/08/2022	06/08/2022	Professor, Mayo Clinic College of Medicine	Special Government Employee (SGE) Member
Dasarathy, Srinivasan	06/08/2022	06/08/2022	Director, Liver Metabolism Research	Special Government Employee (SGE) Member
Desai, Seemal	10/01/2017	09/30/2025	Founder and Medical Director Innovative Dermatology	Special Government Employee (SGE) Member
Dmochowski, Roger	06/08/2022	06/08/2022	Professor of Urology and Surgery, Vanderbilt University Medical Center	Special Government Employee (SGE) Member
Eisenberg, David	06/08/2022	06/08/2022	Associate Director, Division of Family Planning, Washington University in St. Louis School of Medicine	Special Government Employee (SGE) Member
Evans, Scott	06/08/2022	06/08/2022	Professor and Chairman ad interim Department of Pulmonary Medicine University of Texas MD Anderson Cancer Center	Special Government Employee (SGE) Member

Fensky, Timothy	10/01/2018	09/30/2026	Chief Pharmacy Operations Officer, Sullivan's Pharmacy and Medical Supply, Inc., National Assoc. of Boards of Pharmacy	Representative Member
Fusco-Walker, Sandra	10/29/2019	09/30/2023	CONSUMER REPRESENTATIVE, Allergy & Asthma Network	Special Government Employee (SGE) Member
Garcia, Jorge	06/08/2022	06/08/2022	Professor of Medicine and Urology Genitourinary Medical Oncology Program, Case Western Reserve University	Special Government Employee (SGE) Member
Green, Brian	06/08/2022	06/08/2022	Associate Professor, Dermatology, Penn State Health Milton S. Hershey Medical Center	Special Government Employee (SGE) Member
Green, Richard	06/08/2022	06/08/2022	Director of Radiopharmacy Practice Cardinal Health Nuclear and Precision Health	Representative Member
Gulur, Padma	12/18/2020	09/30/2024	Professor of Anesthesiology, Duke University Health System	Special Government Employee (SGE) Member
Gupta, Anita	12/18/2020	09/30/2024	Assistant Professor, Adjunct Johns Hopkins School of Medicine. Chief Executive Officer, Strata Group, Inc.	Special Government Employee (SGE) Member
Gura, Kathleen	12/18/2020	09/30/2024	Manager, Pharmacy Clinical Research Program, Boston Children's Hospital	Special Government Employee (SGE) Member
Lewis, Vivian	06/08/2022	06/08/2022	Professor Emerita, Obstetrics and Gynecology University of Rochester School of Medicine and Dentistry	Special Government Employee (SGE) Member
Lindsay, Michael	06/08/2022	06/08/2022	Director Division Maternal Fetal Medicine Emory University	Special Government Employee (SGE) Member

Margolis, David	06/08/2022	06/08/2022	Professor of Dermatology, University of Pennsylvania	Special Government Employee (SGE) Member
McElhiney, Linda	11/14/2019	09/30/2023	Team Lead Compounding Pharmacist, Indiana University Health Compounding Pharmacy	Special Government Employee (SGE) Member
Nieva, Jorge	06/08/2022	06/08/2022	Section Head, Solid Tumors. Norris Comprehensive Cancer Center	Special Government Employee (SGE) Member
Patel, Kuldip	12/22/2020	09/30/2024	Senior Associate Chief Pharmacy Officer, Duke University Hospital	Special Government Employee (SGE) Member
Rebello, Elizabeth	10/01/2018	09/30/2026	Professor, Department of Anesthesiology and Perioperative Medicine, MD Anderson Cancer Center	Special Government Employee (SGE) Member
Serumaga, Brian	04/23/2022	09/30/2026	Senior Manager, Personalized Medicines United States Pharmacopeial Convention	Representative Member
Sun, Jeanne	10/01/2018	11/05/2021	Counsel, US Pharmacopeial Convention	Representative Member
Vaida, Allen	06/03/2021	09/30/2025	Former Executive Vice President, Institute for Safe Medication Practices	Special Government Employee (SGE) Member

Number of Committee Members Listed: 29

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 Committee shall provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and make 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 Pharmacy Compounding 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?
91

Number of Recommendations Comments
The Committee made 91 recommendations from FY-12 through FY-22. The Committee was re-established in FY-12.

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 or 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 an investigational new medical product.

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

NA