2026 Current Fiscal Year Report: Pharmacy Compounding Advisory Committee

Report Run Date: 06/14/2026 06:05:33 AM

1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2026

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	04/25/2024	04/25/2026	

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
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. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	$0.00	$0.00
18d. Other (all other funds not captured by any other cost category)	$0.00	$0.00
18e. Total Costs	$0.00	$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

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 and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. These members will include representatives from the National Association of Boards of Pharmacy (NABP), the United States Pharmacopeia (USP), pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations. 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-25, the Committee held two meetings. On October 29, 2024, the Committee discussed the following 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): ibutamoren mesylate, L-theanine, ipamorelin-related bulk drug substances (ipamorelin acetate and ipamorelin (free base)), and kisspeptin-10. 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: hydroxyprogesterone caproate: all drug products containing hydroxyprogesterone caproate to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous birth. In the session regarding L-theanine, the majority of the members (1 Yeses to 12 Noes) voted against placing L-theanine on the 503A Bulks List. In the session regarding Ibutamoren mesylate, the majority of committee members (1 Yeses to 13 Noes) voted against placing Ibutamoren mesylate to the 503A Bulks List. In the session regarding Ipamorelin-related bulk drug substances, the majority of the members (0 Yeses, 12 Noes, 1 abstention) voted against placing Ipamorelin (free base) on the 503A Bulks List; and the majority of the members (0 Yeses, 12 Noes, 1 abstention) voted against placing Ipamorelin acetate on the 503A Bulks List. In the session regarding Kisspeptin-10, the Committee (11 members) unanimously agreed that Kisspeptin-10 should not be included on the 503A Bulks List. In the final session regarding Hydroxyprogesterone caproate, the Committee (10 members) unanimously agreed that all drug products containing hydroxyprogesterone caproate to reduce the risk of preterm birth in women with a singleton

pregnancy who have a history of singleton spontaneous preterm birth be ADDED to the Withdrawn or Removed List based on lack of efficacy concerns noted in the presentations. Agency Action: The Agency is reviewing recommendations made at the meeting. On December 4, 2024, the Committee discussed the following 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): AOD-9604-related bulk drug substances (AOD-9604 acetate, and AOD-9604 (free base)), CJC-1295-related bulk drug substances (CJC-1295 (free base), CJC-1295 acetate, CJC-1295 with drug affinity complex (DAC) (free base), CJC-1295 DAC acetate, and CJC-1295 DAC trifluoroacetate)), and Thymosin alpha-1-related bulk drug substances (Thymosin alpha-1 acetate, and Thymosin alpha-1 (free base)). In the session regarding CJC-1295-related bulk drug substances, the Committee (13 members) unanimously agreed that CJC-1295 (free base), CJC-1295 DAC (free base), CJC-1295 DAC acetate, and CJC-1295 DAC trifluoroacetate should not be included on the 503A Bulks List; the majority of the members (1 Yes to 12 Noes) voted against placing CJC-1295 acetate on the 503A Bulks List. In the session regarding AOD-9604-related bulk drug substances, the Committee (12 members) unanimously agreed that AOD-9604 (free base) and AOD-9604 acetate should not be included on the 503A Bulks List. In the session regarding

Thymosin alpha-1-related bulk drug substances, the majority of the members (4 Yes to 17 Noes) voted against placing Thymosin alpha-1 (free base) and Thymosin alpha-1 acetate on the 503A Bulks List. 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-26.

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. They provide advice and input that FDA considers as part of its regulatory decision-making. 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-25.

21. Remarks
There were no reports required for this Committee in FY-25.

Designated Federal Officer
Takyiah Stevenson Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Bogner, Robin	12/18/2020	09/30/2026	Professor, University of Connecticut School of Pharmacy	Special Government Employee (SGE) Member
Fensky, Timothy	10/01/2018	09/30/2026	Chief Pharmacy Operations Officer, Sullivan’s Pharmacy and Medical Supply, Inc., Sullivan's Health Care, Inc.	Representative Member

Gura, Kathleen	12/18/2020	09/30/2028	Assistant Professor of Pediatrics, Harvard Medical School, Manager, Pharmacy Clinical Research Program, Boston Children's Hospital	Special Government Employee (SGE) Member
McElhiney, Linda	11/14/2019	09/30/2027	Team Lead Compounding Pharmacist Indiana University Health	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
Staas, Donnette	02/08/2024	10/31/2027	Vice President, Regulatory Strategy Jazz Pharmaceuticals	Representative Member

Number of Committee Members Listed: 7

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 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?
106

Number of Recommendations Comments
The Committee made 106 recommendations from FY-12 through FY-25. 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