FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting
July 23-24, 2026

DRAFT AGENDA

*During the **morning session**, the committee will discuss the following bulk drug substances being considered for inclusion on the list of bulk drug substances that can be used to compound drug products in accordance with section 503A of the FD&C Act: BPC-related bulk drug substances (BPC-157 (free base) / BPC-157 acetate) and KPV-related bulk drug substances (KPV (free base) / KPV acetate).*

July 23, 2026, AM Session

8:00 a.m.	Call to Order and Introduction of Committee	**Brian Serumaga, PhD** Acting Chairperson, PCAC
8:10 a.m.	Conflict of Interest Statement	**Takyiah Stevenson, PharmD** Designated Federal Officer, PCAC
8:15 a.m.	**FDA INTRODUCTORY REMARKS**	**Matthew Lash, JD** Acting Director Office of Compounding Quality and Compliance (OCQC) Office of Compliance (OC), CDER, FDA
8:30 a.m.	FDA Bulk Drug Substance Discussion of Conflated Bulks and Common Name Challenges	**Russell Wesdyk, BS, MBA** Associate Director for Regulatory Affairs Office of Product Quality Assessment II (OPQAII) Office of Pharmaceutical Quality (OPQ), CDER, FDA
8:50 a.m.	Clarifying Questions from the Committee	
8:55 a.m.	**SECTION 503A BULK DRUG SUBSTANCES LIST – BPC-157-RELATED BULK DRUG SUBSTANCES (BPC-157 (FREE BASE) AND BPC-157 ACETATE)**	
8:55 a.m.	**OPEN PUBLIC HEARING**	
10:55 a.m.	**BREAK**	
11:05 a.m.	**FDA PRESENTATION**	**Elizabeth Hankla, PharmD** Senior Clinical Analyst Pharmacy Compounding Review Team (PCRT) Office of Specialty Medicine (OSM) Office of New Drugs (OND), CDER, FDA **Mai Tu, PhD** Senior Pharmaceutical Scientist OPQAII, OPQ, CDER, FDA **Olubukola Adeyemi, PharmD, BCPS** Consumer Safety Officer OCQC, OC, CDER, FDA

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DRAFT AGENDA (cont.)

SECTION 503A BULK DRUG SUBSTANCES LIST – BPC-RELATED BULK DRUG SUBSTANCES (BPC-157 (FREE BASE) AND BPC-157 ACETATE) (CONT.)

11:35 a.m. Clarifying Questions from the Committee

11:45 a.m. **COMMITTEE DISCUSSION AND VOTE**

12:05 p.m. **BREAK**

12:15 p.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – KPV-RELATED BULK DRUG SUBSTANCES (KPV (FREE BASE) AND KPV ACETATE)**

12:15 p.m. **OPEN PUBLIC HEARING**

1:00 p.m. **FDA PRESENTATION**

Emily Kneeream, PharmD
Clinical Analyst
PCRT, OSM, OND, CDER, FDA

Jing Li, PhD
Regulatory Scientific Reviewer
OPQAII, OPQ, CDER, FDA

Nga-Lai Poon, PharmD
Regulatory Specialist
OCQC, OC, CDER, FDA

1:25 p.m. Clarifying Questions from the Committee

1:35 p.m. **COMMITTEE DISCUSSION AND VOTE**

1:55 p.m. **LUNCH**

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FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting
July 23- 24, 2026

DRAFT AGENDA (cont.)

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*During the **afternoon session**, the committee will discuss 2 additional bulk drug substances being considered for inclusion on the list of bulk drug substances that can be used to compound drug products in accordance with section 503A of the FD&C Act: TB-500-related bulk drug substances (TB-500 (free base)/TB-500 acetate) and MOTS-c-related bulk drug substances (MOTS-c (free base)/MOTS-c acetate).*

July 23, 2026, PM Session

2:55 p.m.	**SECTION 503A BULK DRUG SUBSTANCES LIST – TB-500-RELATED BULK DRUG SUBSTANCES (TB-500 (FREE BASE) AND TB-500 ACETATE)**	
2:55 p.m.	**OPEN PUBLIC HEARING**	
3:40 p.m.	**FDA PRESENTATION**	**Emily Kneeream, PharmD** Clinical Analyst PCRT, OSM, OND, CDER, FDA **Bini Mathew, PhD** Pharmaceutical Scientist OPQAII, OPQ, CDER, FDA **Ashlee Mattingly, PharmD, MPH** Consumer Safety Officer OCQC, OC, CDER, FDA
4:00 p.m.	Clarifying Questions from the Committee	
4:10 p.m.	**COMMITTEE DISCUSSION AND VOTE**	
4:30 p.m.	**BREAK**	
4:40 p.m.	**SECTION 503A BULK DRUG SUBSTANCES LIST – MOTS-C-RELATED BULK DRUG SUBSTANCES (MOTS-C (FREE BASE) AND MOTS-C ACETATE)**	
4:40 p.m.	**OPEN PUBLIC HEARING**	
5:25 p.m.	**FDA PRESENTATION**	**Marianne San Antonio, DO** Physician PCRT, OSM, OND, CDER, FDA **Jing Li, PhD** Regulatory Scientific Reviewer OPQAII, OPQ, CDER, FDA **Nga-Lai Poon, PharmD** Regulatory Specialist OCQC, OC, CDER, FDA

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DRAFT AGENDA (cont.)

SECTION 503A BULK DRUG SUBSTANCES LIST – MOTS-C-RELATED BULK DRUG SUBSTANCES (MOTS-C (FREE BASE) AND MOTS-C ACETATE) (CONT.)

5:50 p.m. Clarifying Questions from the Committee

6:00 p.m. **COMMITTEE DISCUSSION AND VOTE**

6:20 p.m. **ADJOURNMENT**

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FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting
July 23- 24, 2026

DRAFT AGENDA (cont.)

*During the **morning session**, the committee will discuss the following bulk drug substances being considered for inclusion on the list of bulk drug substances that can be used to compound drug products in accordance with section 503A of the FD&C Act: Emideltide-related bulk drug substances (Emideltide (free base) / Emideltide acetate) and Epitalon-related bulk drug substances (Epitalon (free base) / Epitalon acetate).*

July 24, 2026, AM Session

8:00 a.m.	Call to Order and Introduction of Committee	**Brian Serumaga, PhD** Acting Chairperson, PCAC
8:10 a.m.	Conflict of Interest Statement	**Takyiah Stevenson, PharmD** Designated Federal Officer, PCAC
8:15 a.m.	FDA Introductory Remarks	**Matthew Lash, JD** Acting Director OCQC, OC, CDER, FDA
8:30 a.m.	FDA Bulk Drug Substance Discussion of Conflated Bulks and Common Name Challenges	**Russell Wesdyk, BS, MBA** Associate Director for Regulatory Affairs OPQAII, OPQ, CDER, FDA
8:50 a.m.	Clarifying Questions from the Committee	
8:55 a.m.	**SECTION 503A BULK DRUG SUBSTANCES LIST – EMIDELTIDE-RELATED BULK DRUG SUBSTANCES (EMIDELTIDE (FREE BASE) AND EMIDELTIDE ACETATE)**	
8:55 a.m.	**OPEN PUBLIC HEARING**	
9:55 a.m.	**FDA PRESENTATION**	**Katie Park, PharmD, MPH** Clinical Analyst PCRT, OSM, OND, CDER, FDA **Hong Ding, PhD** Regulatory Scientific Reviewer OPQAII, OPQ, CDER, FDA **Jamiele Mattocks, PharmD** Consumer Safety Officer OCQC, OC, CDER, FDA
10:35 a.m.	Clarifying Questions from the Committee	
10:45 a.m.	**COMMITTEE DISCUSSION AND VOTE**	
11:05 a.m.	**BREAK**	

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DRAFT AGENDA (cont.)

11:15 a.m.	**SECTION 503A BULK DRUG SUBSTANCES LIST – EPITALON-RELATED BULK DRUG SUBSTANCES (EPITALON (FREE BASE) AND EPITALON ACETATE)**	
11:15 a.m.	**OPEN PUBLIC HEARING**	
12:15 p.m.	**FDA PRESENTATION**	**Katie Park, PharmD, MPH** Clinical Analyst PCRT, OSM, OND, CDER, FDA **Nathaniel Iloanusi, PhD, RPH** Regulatory Scientific Reviewer OPQAII, OPQ, CDER, FDA **Ashlee Mattingly, PharmD, MPH** Consumer Safety Officer OCQC, OC, CDER, FDA
12:40 p.m.	Clarifying Questions from the Committee	
12:50 p.m.	**COMMITTEE DISCUSSION AND VOTE**	
1:10 p.m.	**LUNCH**	

DRAFT

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting
July 23- 24, 2026

DRAFT AGENDA (cont.)

*During the **afternoon session**, the committee will discuss one additional bulk drug substance being considered for inclusion on the list of bulk drug substances that can be used to compound drug products in accordance with section 503A of the FD&C Act: Semax-related bulk drug substances (Semax (free base)/Semax acetate).*

July 24, 2026, PM Session

2:10 p.m.	**SECTION 503A BULK DRUG SUBSTANCES LIST – SEMAX-RELATED BULK DRUG SUBSTANCES (SEMAX (FREE BASE) AND SEMAX ACETATE)**	
2:10 p.m.	**OPEN PUBLIC HEARING**	
3:10 p.m.	**FDA PRESENTATION**	**Marianne San Antonio, DO** Physician PCRT, OSM, OND, CDER, FDA **Jing Li, PhD** Regulatory Scientific Reviewer OPQAII, OPQ, CDER, FDA **Jamiele Mattocks, PharmD** Consumer Safety Officer OCQC, OC, CDER, FDA
3:45 p.m.	Clarifying Questions from the Committee	
3:55 p.m.	**COMMITTEE DISCUSSION AND VOTE**	
4:15 p.m.	**ADJOURNMENT**	

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