

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting
October 29, 2024

DRAFT AGENDA

*During the **morning session**, the Committee will discuss two 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 FD&C Act: L-theanine and Ibutamoren Mesylate.*

October 29, 2024, AM Session

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| 8:00 a.m. | Call to Order and Introduction of Committee | Padma Gulur, MD, FASA
Chairperson, PCAC |
| 8:10 a.m. | Conflict of Interest Statement | Takyiah Stevenson, PharmD
Designated Federal Officer, PCAC |
| 8:20 a.m. | FDA INTRODUCTORY REMARKS | Frances Gail Bormel, RPh, JD
Director
Office of Compounding Quality and Compliance (OCQC)
Office of Compliance (OC), CDER, FDA |
| 8:30 a.m. | FDA Investigational New Drug and Expanded Access Presentation | Lori Bickel, JD
Regulatory Counsel
Division of Regulatory Policy
Office of New Drug Policy
Office of New Drugs (OND), CDER, FDA |
| 8:40 a.m. | SECTION 503A BULK DRUG SUBSTANCES LIST – L-THEANINE | |
| | NOMINATOR PRESENTATION | |
| | Clarifying Questions from the Committee | |
| | FDA PRESENTATION | Marianne San Antonio, DO
Physician
Pharmacy Compounding Review Team (PCRT)
Office of Specialty Medicine (OSM)
OND, CDER, FDA |
| | Clarifying Questions from the Committee | |
| 9:25 a.m. | OPEN PUBLIC HEARING | |
| 9:40 a.m. | COMMITTEE DISCUSSION AND VOTE | |
| 9:50 a.m. | BREAK | |

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DRAFT AGENDA (cont.)

10:00 a.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – IBUTAMOREN MESYLATE**

NOMINATOR PRESENTATION

Clarifying Questions from the Committee

FDA PRESENTATION

Madeline Wolfert, MD

Physician

PCRT, OSM, OND, CDER, FDA

Clarifying Questions from the Committee

11:10 a.m. **OPEN PUBLIC HEARING**

11:25 a.m. **COMMITTEE DISCUSSION AND VOTE**

11:35 a.m. **LUNCH**

FOOD AND DRUG ADMINISTRATION (FDA)
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Pharmacy Compounding Advisory Committee (PCAC) Meeting
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DRAFT AGENDA (cont.)

During the afternoon session, the Committee will discuss two additional 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 FD&C Act: Ipamorelin-related bulk drug substances (Ipamorelin acetate and Ipamorelin (free base)) and Kisspeptin-10. The Committee will also discuss one drug being considered for inclusion on the list of drug products that may not be compounded because they have been withdrawn or removed from the market because they have been found to be unsafe or not effective (Withdrawn or Removed List, codified at 21 CFR 216.24): Hydroxyprogesterone Caproate.

October 29, 2024, PM Session

12:35 p.m. **FDA IMMUNOGENICITY RISK OF COMPOUNDED PEPTIDES PRESENTATION** **Daniela Verthelyi, MD, PhD**
Supervisory Biologist, Division IV
Office of Pharmaceutical Quality (OPQ), CDER, FDA

12:50 p.m. **BULK DRUG SUBSTANCE DISCUSSION** **Russell Wesdyk, BS, MBA**
Associate Director for Regulatory Affairs
Office of Product Quality Assessment II
OPQ, CDER, FDA

Clarifying Questions from the Committee

1:15 p.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – IPAMORELIN-RELATED BULK DRUG SUBSTANCES (IPAMORELIN ACETATE AND IPAMORELIN (FREE BASE))**

FDA PRESENTATION **Katie Park, PharmD, MPH**
Clinical Analyst
PCRT, OSM, OND, CDER, FDA

And

Russell Wesdyk, BS, MBA

Clarifying Questions from the Committee

1:45 p.m. **OPEN PUBLIC HEARING**

2:05 p.m. **COMMITTEE DISCUSSION AND VOTE**

2:15 p.m. **BREAK**

2:25 p.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – KISSPEPTIN-10**

NOMINATOR PRESENTATION

Clarifying Questions from the Committee

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting
October 29, 2024

DRAFT AGENDA (cont.)

SECTION 503A BULK DRUG SUBSTANCES LIST – KISSPEPTIN-10 (CONT.)

FDA PRESENTATION

Elizabeth Hankla, PharmD
Senior Clinical Analyst
PCRT, OSM, OND, CDER, FDA

Clarifying Questions from the Committee

3:10 p.m. **OPEN PUBLIC HEARING**

3:25 p.m. **COMMITTEE DISCUSSION AND VOTE**

3:35 p.m. **BREAK**

3:45 p.m. Conflict of Interest Statement

Takyiah Stevenson, PharmD
Designated Federal Officer, PCAC

3:50 p.m. **WITHDRAWN OR REMOVED LIST
PROCESS**

Gabrielle Cosel, MSc
Director
Division of Compounding Policy and Outreach
OCQC, OC, CDER, FDA

4:00 p.m. **DRUGS TO BE CONSIDERED FOR THE WITHDRAWN OR REMOVED LIST –
HYDROXYPROGESTERONE CAPROATE**

FDA PRESENTATION

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

Clarifying Questions from the Committee

4:20 p.m. **OPEN PUBLIC HEARING**

4:35 p.m. **COMMITTEE DISCUSSION AND VOTE**

4:45 p.m. **ADJOURNMENT**