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

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

AGENDA

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*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

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**	

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)
Center for Drug Evaluation and Research (CDER)

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

AGENDA (cont.)

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*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	

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**	