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

Pharmacy Compounding Advisory Committee (PCAC) Meeting
December 4, 2024

AGENDA

During the morning session, the committee will discuss 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 FD&C Act: 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 AOD-9604-related bulk drug substances (AOD-9604 acetate, and AOD-9604 (free base)).

December 4, 2024, AM Session

8:00 a.m.	Call to Order and Introduction of Committee	**Elizabeth Rebello, RPh, MD, FASA, CPPS, CMQ** 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**	**Frances Gail Bormel, RPh, JD** Director Office of Compounding Quality and Compliance (OCQC) Office of Compliance (OC), CDER, FDA
8:25 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
8:35 a.m.	FDA Immunogenicity Risk of Compounded Peptides Presentation	**Daniela Verthelyi, MD, PhD** Supervisory Senior Biomedical Research and Biomedical Product Assessment Service Expert Office of Pharmaceutical Quality (OPQ), CDER, FDA
8:50 a.m.	FDA Bulk Drug Substance Discussion	**Russell Wesdyk, BS, MBA** Associate Director for Regulatory Affairs Office of Product Quality Assessment II (OPQAII) OPQ, CDER, FDA
	Clarifying Questions from the Committee	

AGENDA (cont.)

9:15 a.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – 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)**

FDA PRESENTATION

Marianne San Antonio, DO
Physician
Pharmacy Compounding Review Team (PCRT)
Office of Specialty Medicine (OSM)
OND, CDER, FDA

And

Mai Tu, PhD
Senior Pharmaceutical Scientist
OPQAII, OPQ, CDER, FDA

Clarifying Questions from the Committee

10:00 a.m. **OPEN PUBLIC HEARING**

10:20 a.m. **COMMITTEE DISCUSSION AND VOTE**

10:40 a.m. **BREAK**

10:50 a.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – AOD-9604- RELATED BULK DRUG SUBSTANCES (AOD-9604 ACETATE, AND AOD-9604 (FREE BASE))**

FDA PRESENTATION

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

And

Bini Mathew, PhD
Pharmaceutical Scientist
OPQAII, OPQ, CDER, FDA

Clarifying Questions from the Committee

11:25 a.m. **OPEN PUBLIC HEARING**

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

12:05 p.m. **LUNCH**

FOOD AND DRUG ADMINISTRATION (FDA)
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Pharmacy Compounding Advisory Committee (PCAC) Meeting
December 4, 2024

AGENDA (cont.)

During the afternoon session, the committee will discuss 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: Thymosin alpha-1-related bulk drug substances (Thymosin alpha-1 acetate and Thymosin alpha-1 (free base)).

December 4, 2024, PM Session

1:00 p.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – THYMOSIN ALPHA-1-RELATED BULK DRUG SUBSTANCES (THYMOSIN ALPHA-1 ACETATE, AND THYMOSIN ALPHA-1 (FREE BASE))**

FDA PRESENTATION

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

And

Jing Li, PhD
Chemist
OPQAII, OPQ, CDER, FDA

Clarifying Questions from the Committee

2:20 p.m. **BREAK**

2:30 p.m. **OPEN PUBLIC HEARING**

2:50 p.m. **COMMITTEE DISCUSSION AND VOTE**

4:00 p.m. **ADJOURNMENT**