

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

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

DRAFT 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

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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 |
| 8:15 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 (OPQAI)
OPQ, CDER, FDA |

Clarifying Questions from the Committee

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

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

DRAFT 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
OPQAIL, 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
OPQAIL, 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**

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DRAFT 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
OPQAI, 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**