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

***Pharmacy Compounding Advisory Committee (PCAC) Meeting***
June 8, 2022

**DRAFT 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: enclomiphene citrate and glutathione.*

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**June 8, 2022, AM Session**

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| 9:30 a.m. | Call to Order | **Allen J. Vaida, BSc, PharmD, FASHP**<br>Acting Chairperson, PCAC |
| 9:35 a.m. | Introduction of Committee and Conflict of Interest Statement | **Takyiah Stevenson, PharmD**<br>Designated Federal Officer, PCAC |
| 9:45 a.m. | **FDA INTRODUCTORY REMARKS** | **Frances Gail Bormel, RPh, JD**<br>Director<br>Office of Compounding Quality and Compliance (OCQC)<br>Office of Compliance (OC), CDER, FDA |
| 9:55 a.m. | FDA Investigational New Drug (IND)/Expanded Access Presentation | **Lori Bickel, JD**<br>Regulatory Counsel<br>Division of Medical Policy Development (DMPD)<br>Office of Medical Policy (OMP), CDER, FDA |
| 10:05 a.m. | **SECTION 503A BULK DRUG SUBSTANCES LIST – ENCLOMIPHENE CITRATE** | |
| | **FDA PRESENTATION** | **Madeline Wolfert, MD**<br>Physician<br>Pharmacy Compounding Review Team<br>Office of Specialty Medicine (OSM)<br>Office of New Drugs (OND), CDER, FDA |
| | Clarifying Questions from the Committee | |
| | **NOMINATOR PRESENTATIONS** | **Marwa Elsaied, PharmD, RPh and Thomas Masterson III, MD**<br>Empower Pharmacy |
| | Clarifying Questions from the Committee | |
| 10:40 a.m. | **OPEN PUBLIC HEARING** | |
| 10:55 a.m. | **COMMITTEE DISCUSSION AND VOTE** | |
| 11:05 a.m. | **BREAK** | |

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***Pharmacy Compounding Advisory Committee (PCAC) Meeting***
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**DRAFT AGENDA (cont.)**

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| 11:15 a.m. | **SECTION 503A BULK DRUG SUBSTANCES LIST – GLUTATHIONE** | |
| | **FDA PRESENTATION** | **Emily Kneeream, PharmD**<br>Clinical Analyst<br>Pharmacy Compounding Review Team<br>OSM, OND, CDER, FDA |
| | Clarifying Questions from the Committee | |
| | **NOMINATOR PRESENTATION** | **A.J. Day, PharmD**<br>Professional Compounding Centers of America and National Community Pharmacists Association |
| | Clarifying Questions from the Committee | |
| 12:15 p.m. | **OPEN PUBLIC HEARING** | |
| 12:30 p.m. | **COMMITTEE DISCUSSION AND VOTE** | |
| 12:40 p.m. | **LUNCH** | |

**FOOD AND DRUG ADMINISTRATION (FDA)**
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**DRAFT 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: ammonium tetrathiomolybdate and ferric subsulfate. 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): lorcaserin hydrochloride.*

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**June 8, 2022, PM Session**

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| 1:25 p.m. | **SECTION 503A BULK DRUG SUBSTANCES LIST – AMMONIUM TETRATHIOMOLYBDATE (ATTM)** | |
| | **FDA PRESENTATION** | **Raquel Tapia, MD**<br>Physician<br>Pharmacy Compounding Review Team<br>OSM, OND, CDER, FDA |
| | Clarifying Questions from the Committee | |
| | **NOMINATOR PRESENTATION** | **Mark Rosenberg, MD**<br>Pharmacy Solutions |
| | Clarifying Questions from the Committee | |
| 2:25 p.m. | **OPEN PUBLIC HEARING** | |
| 2:40 p.m. | **COMMITTEE DISCUSSION AND VOTE** | |
| 2:50 p.m. | **BREAK** | |
| 3:05 p.m. | **SECTION 503A BULK DRUG SUBSTANCES LIST – FERRIC SUBSULFATE** | |
| | **FDA PRESENTATION** | **Anam Tariq, DO, MHS**<br>Physician<br>Pharmacy Compounding Review Team<br>OSM, OND, CDER, FDA |
| | Clarifying Questions from the Committee | |
| | **NOMINATOR PRESENTATION** | |
| | Clarifying Questions from the Committee | |
| 3:45 p.m. | **OPEN PUBLIC HEARING** | |
| 4:00 p.m. | **COMMITTEE DISCUSSION AND VOTE** | |

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

***Pharmacy Compounding Advisory Committee (PCAC) Meeting***
June 8, 2022

**DRAFT AGENDA (cont.)**

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| 4:10 p.m. | **BREAK** | |
| 4:20 p.m. | Conflict of Interest Statement | **Takyiah Stevenson, PharmD**<br>Designated Federal Officer, PCAC |
| 4:25 p.m. | **WITHDRAWN OR REMOVED LIST PROCESS** | **Gabrielle Cosel, MSc**<br>Director<br>Division of Compounding Policy and Outreach<br>OCQC, OC, CDER, FDA |
| 4:35 p.m. | **DRUGS TO BE CONSIDERED FOR THE WITHDRAWN OR REMOVED LIST – LORCASERIN HYDROCHLORIDE** | |
| | **FDA PRESENTATION** | **Marianne San Antonio, DO**<br>Physician<br>Pharmacy Compounding Review Team<br>OSM, OND, CDER, FDA |
| | Clarifying Questions from the Committee | |
| 4:50 p.m. | **OPEN PUBLIC HEARING** | |
| 5:05 p.m. | **COMMITTEE DISCUSSION AND VOTE** | |
| 5:15 p.m. | **ADJOURNMENT** | |