

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

***Pharmacy Compounding Advisory Committee (PCAC) Meeting***  
June 9, 2021

**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: melatonin and methylcobalamin.*

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**June 9, 2021, AM Session**

- 9:45 a.m. Call to Order **Padma Gulur, MD, FASA**  
Chairperson, PCAC
- 9:50 a.m. Introduction of Committee and  
Conflict of Interest Statement **Takyiah Stevenson, PharmD**  
Designated Federal Officer, PCAC
- 10:00 a.m. **FDA INTRODUCTORY REMARKS** **Frances Gail Bormel, RPh, JD**  
Director  
Office of Compounding Quality and Compliance  
(OCQC)  
Office of Compliance (OC), CDER, FDA
- 10:10 a.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – MELATONIN**  
*Melatonin* **Suhail Kasim, MD, MPH**  
Lead Physician  
Pharmacy Compounding Review Team  
Office of Specialty Medicine (OSM)  
Office of New Drugs (OND), CDER, FDA
- Clarifying Questions from the Committee
- NOMINATOR PRESENTATIONS**
- Clarifying Questions from the Committee
- 10:45 a.m. **OPEN PUBLIC HEARING**
- 11:00 a.m. **COMMITTEE DISCUSSION AND VOTE**
- 11:10 a.m. **BREAK**
- 11:25 a.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – METHYLCOBALAMIN**  
*Methylcobalamin* **Susan Johnson, PharmD, PhD**  
Clinical Reviewer  
Pharmacy Compounding Review Team  
OSM, OND, CDER, FDA

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**DRAFT AGENDA (cont.)**

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Clarifying Questions from the Committee

**NOMINATOR PRESENTATIONS**

**Richard E. Frye, MD, PhD**  
Professional Compounding Centers of America

**A.J. Day, PharmD**  
National Community Pharmacists Association and  
Alliance for Pharmacy Compounding

Clarifying Questions from the Committee

12:25 p.m. **OPEN PUBLIC HEARING**

12:40 p.m. **COMMITTEE DISCUSSION AND VOTE**

12:50 p.m. **LUNCH**

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***Pharmacy Compounding Advisory Committee (PCAC) Meeting***  
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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: choline chloride and oxitriptan. 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): neomycin sulfate.*

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**June 9, 2021, PM Session**

1:35 p.m.      **SECTION 503A BULK DRUG SUBSTANCES LIST – CHOLINE CHLORIDE**

*Choline Chloride*

**Suhail Kasim, MD, MPH**  
Lead Physician  
Pharmacy Compounding Review Team  
OSM, OND, CDER, FDA

Clarifying Questions from the Committee

**NOMINATOR PRESENTATIONS**

**Paul S. Anderson, ND**  
American Association of Naturopathic Physicians

Clarifying Questions from the Committee

2:15 p.m.      **OPEN PUBLIC HEARING**

2:30 p.m.      **COMMITTEE DISCUSSION AND VOTE**

2:40 p.m.      **BREAK**

2:55 p.m.      **SECTION 503A BULK DRUG SUBSTANCES LIST – OXITRIPTAN**

*Oxitriptan*

**Madeline Wolfert, MD**  
Physician  
Pharmacy Compounding Review Team  
OSM, OND, CDER, FDA

Clarifying Questions from the Committee

3:35 p.m.      **OPEN PUBLIC HEARING**

3:50 p.m.      **COMMITTEE DISCUSSION AND VOTE**

4:00 p.m.      **BREAK**

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

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

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- 4:15 p.m.     **WITHDRAWN OR REMOVED LIST PROCESS**     **Gabrielle Cosel**  
Director (Acting)  
Division of Compounding Policy and Outreach  
OCQC, OC, CDER, FDA
- 4:25 p.m.     **DRUGS TO BE CONSIDERED FOR THE WITHDRAWN OR REMOVED LIST – NEOMYCIN SULFATE**
- Neomycin sulfate*
- Jae Ho Hong, MD**  
Medical Officer  
Division of Anti-Infectives  
Office of Infectious Diseases  
OND, CDER, FDA
- Clarifying Questions from the Committee
- 4:40 p.m.     **OPEN PUBLIC HEARING**
- 4:55 p.m.     **COMMITTEE DISCUSSION AND VOTE**
- 5:05 p.m.     **ADJOURNMENT**