

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

***Pharmacy Compounding Advisory Committee (PCAC) Meeting***

June 9, 2021

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

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**AGENDA (cont.)**

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Clarifying Questions from the Committee

**NOMINATOR PRESENTATIONS**

**A.J. Day, PharmD**

National Community Pharmacists Association and  
Alliance for Pharmacy Compounding

**Richard E. Frye, MD, PhD**

Professional Compounding Centers of America

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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**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***  
June 9, 2021

**AGENDA (cont.)**

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- 4:15 p.m.      Conflict of Interest Statement                      **Takyiah Stevenson, PharmD**  
Designated Federal Officer, PCAC
- 4:20 p.m.      **WITHDRAWN OR REMOVED LIST**                      **Gabrielle Cosel**  
**PROCESS**    Director (Acting)  
Division of Compounding Policy and Outreach  
OCQC, OC, CDER, FDA
- 4:30 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
- 4:45 p.m.      **OPEN PUBLIC HEARING**
- 5:00 p.m.      **COMMITTEE DISCUSSION AND VOTE**
- 5:10 p.m.      **ADJOURNMENT**