AGENDA

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.

June 9, 2021, AM Session

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<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter/Role</th>
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<tr>
<td>9:45 a.m.</td>
<td>Call to Order</td>
<td>Padma Gulur, MD, FASA, Chairperson, PCAC</td>
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<td>9:50 a.m.</td>
<td>Introduction of Committee and Conflict of Interest Statement</td>
<td>Takyiah Stevenson, PharmD, Designated Federal Officer, PCAC</td>
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<td>10:00 a.m.</td>
<td>FDA Introductory Remarks</td>
<td>Frances Gail Bormel, RPh, JD, Director, Office of Compounding Quality and Compliance (OCQC), Office of Compliance (OC), CDER, FDA</td>
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<tr>
<td>10:10 a.m.</td>
<td>Section 503A Bulk Drug Substances List – Melatonin</td>
<td>Suhail Kasim, MD, MPH, Lead Physician, Pharmacy Compounding Review Team, Office of Specialty Medicine (OSM), Office of New Drugs (OND), CDER, FDA</td>
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<td>Clarifying Questions from the Committee</td>
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<td>NOMINATOR PRESENTATIONS</td>
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<td>Clarifying Questions from the Committee</td>
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<tr>
<td>10:45 a.m.</td>
<td>Open Public Hearing</td>
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<tr>
<td>11:00 a.m.</td>
<td>Committee Discussion and Vote</td>
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<td>11:10 a.m.</td>
<td>Break</td>
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<tr>
<td>11:25 a.m.</td>
<td>Section 503A Bulk Drug Substances List – Methylcobalamin</td>
<td>Susan Johnson, PharmD, PhD, Clinical Reviewer, Pharmacy Compounding Review Team, OSM, OND, CDER, FDA</td>
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</table>
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**
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.

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
AGENDA (cont.)

4:15 p.m.  Conflict of Interest Statement  
Takyiah Stevenson, PharmD  
Designated Federal Officer, PCAC

4:20 p.m.  WITHDRAWN OR REMOVED LIST PROCESS  
Gabrielle Cosel  
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