During the morning session, the committee will review proposed revisions to the list of drug products that may not be compounded because they have been found to be unsafe or not effective (withdrawn or removed list, codified at 21 CFR 216.24) and vote on whether or not to include each drug product that was included in a proposed rule published in July 2014 (79 FR 37687).

February 23, 2015

8:30 a.m. Call to Order and Introduction of Committee

Jürgen Venitz, MD, PhD
Chairperson, PCAC

8:45 a.m. Conflict of Interest Statement

Jayne E. Peterson, BS Pharm, JD
Designated Federal Officer (acting), PCAC

8:55 a.m. FDA Introductory Remarks and Overview of Withdrawn and Removed List

Jane A. Axelrad, JD
Associate Director for Policy, CDER and Agency Lead on Compounding

FDA Presentations

9:15 a.m. Identification of Drugs Withdrawn or Removed from the Market for Safety Reasons

Clarifying Questions from the Committee

Mwango A. Kashoki, MD, MPH
Associate Director for Safety, Office of New Drugs (OND), Immediate Office, CDER, FDA

9:30 a.m. Adenosine Phosphate

Clarifying Questions from the Committee

Nancy Xu, MD
Medical Officer, Division of Cardiovascular and Renal Products, Office of Drug Evaluation (ODE) I, OND, CDER, FDA

9:45 a.m. Chloramphenicol

Clarifying Questions from the Committee

Dmitri Iarikov, MD, PhD
Clinical Team Leader (acting)
Division of Anti-Infective Products, Office of Antimicrobial Products (OAP)
OND, CDER, FDA

10:00 a.m. BREAK

10:15 a.m. OPEN PUBLIC HEARING

10:45 a.m. Committee Discussion and Vote on Withdrawn or Removed List

12:15 p.m. LUNCH
During the afternoon session and continuing to the next day, the committee will discuss substances nominated for inclusion on the list of bulk drug substances that may be used to compound drug products in accordance with section 503A of the FD&C Act.

February 23, 2015

1:15 p.m. Call to Order

1:25 p.m. Conflict of Interest Statement

Jürgen Venitz, MD, PhD
Chairperson, PCAC

Jayne E. Peterson, BS Pharm, JD
Designated Federal Officer (acting), PCAC

Kalah Auchincloss, JD, MPH
Director (acting), Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER, FDA

1:30 p.m. FDA Introduction to List of Bulk Drug Substances That Can Be Used to Compound Drug Products Under the Conditions of Section 503A

Kalah Auchincloss, JD, MPH
Director (acting), Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER, FDA

1:45 p.m. Committee Discussion of Proposed Criteria for the Section 503A Bulk Drug Substance List

Patricia Brown, MD, FAAD
Medical Officer, Division of Dermatology and Dental Products (DDDP), ODE III
OND, CDER, FDA

Wiley Chambers, MD
Deputy Director, Division of Transplant and Ophthalmology Products
OND, CDER, FDA

2:15 p.m. FDA PRESENTATIONS

SECTION 503A BULK DRUG SUBSTANCES

Clarifying Questions from the Committee

Thymol Iodide

Craig Hitchman, RPh
Academy Director
Fagron North America

Silver Protein Mild

Clarifying Questions from the Committee

3:00 p.m. BREAK

3:15 p.m. NOMINATOR PRESENTATION

Thymol Iodide

Silver Protein Mild

Craig Hitchman, RPh
Academy Director
Fagron North America

3:35 p.m. OPEN PUBLIC HEARING SESSION

3:50 p.m. Committee Discussion and Vote

Thymol Iodide

Silver Protein Mild

5:00 p.m. ADJOURNMENT
The committee will continue to discuss substances nominated for inclusion on the list of bulk drug substances that may be used to compound drug products in accordance with section 503A of the FD&C Act.

### February 24, 2015

<table>
<thead>
<tr>
<th>Time</th>
<th>Item</th>
<th>Presenter/Speaker Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:15 a.m.</td>
<td>Call to Order and Introduction of Committee</td>
<td>Jürgen Venitz, MD, PhD, Chairperson, PCAC</td>
</tr>
<tr>
<td>8:30 a.m.</td>
<td>Conflict of Interest Statement</td>
<td>Jayne E. Peterson, BS Pharm, JD, Designated Federal Officer (acting), PCAC</td>
</tr>
<tr>
<td>8:35 a.m.</td>
<td><strong>FDA Presentations</strong></td>
<td></td>
</tr>
<tr>
<td>8:35 a.m.</td>
<td><strong>Section 503A Bulk Drug Substances</strong></td>
<td></td>
</tr>
<tr>
<td>8:35 a.m.</td>
<td>Squaric Acid Dibutyl Ester</td>
<td>Hon-Sum Ko, MD, FACP, Medical Officer, DDDP, ODE III, OND, CDER, FDA</td>
</tr>
<tr>
<td>8:35 a.m.</td>
<td>Diphenylcyclopropenone</td>
<td></td>
</tr>
<tr>
<td>9:10 a.m.</td>
<td>Clarifying Questions from the Committee</td>
<td></td>
</tr>
<tr>
<td>9:10 a.m.</td>
<td><strong>Nominator Presentations</strong></td>
<td></td>
</tr>
<tr>
<td>9:10 a.m.</td>
<td>Squaric Acid Dibutyl Ester</td>
<td>A. J. Day, PharmD, RPh, Director of Pharmacy Consulting, Professional Compounding Centers of America (PCCA)</td>
</tr>
<tr>
<td>9:10 a.m.</td>
<td>Diphenylcyclopropenone</td>
<td>Craig Hitchman, RPh, Academy Director, Fagron North America</td>
</tr>
<tr>
<td>9:30 a.m.</td>
<td><strong>Open Public Hearing Session</strong></td>
<td></td>
</tr>
<tr>
<td>9:45 a.m.</td>
<td>Committee Discussion and Vote</td>
<td></td>
</tr>
<tr>
<td>9:45 a.m.</td>
<td>Squaric Acid Dibutyl Ester</td>
<td></td>
</tr>
<tr>
<td>9:45 a.m.</td>
<td>Diphenylcyclopropenone</td>
<td></td>
</tr>
<tr>
<td>10:30 a.m.</td>
<td><strong>Break</strong></td>
<td></td>
</tr>
</tbody>
</table>
The committee will continue to discuss substances nominated for inclusion on the list of bulk drug substances that may be used to compound drug products in accordance with section 503A of the FD&C Act.

February 24, 2015

10:55 a.m. **FDA Presentations**

**Section 503A Bulk Drug Substances**

Cantharidin

Patricia Brown, MD, FAAD  
Medical Officer, Division of Dermatology and Dental Products (DDDP), ODE III  
OND, CDER, FDA

Clarifying Questions from the Committee

Piracetam

Kenneth Bergmann, MD  
Medical Officer, Division of Neurology Products  
ODE I, OND, CDER, FDA

Clarifying Questions from the Committee

11:25 a.m. **Nominator Presentations**

Cantharidin

A. J. Day, PharmD, RPh  
PCCA

Piracetam

11:45 a.m. **Open Public Hearing Session**

12:00 p.m. **Lunch**

1:00 p.m. Committee Discussion and Vote

Cantharidin

Piracetam

3:00 p.m. **Adjournment**