During the morning session, the committee will discuss two bulk drug substances nominated for inclusion on the list of bulk drug substances that may be used to compound drugs in accordance with section 503A of the Food, Drug, and Cosmetic Act (FD&C Act): quinacrine hydrochloride and boswellia.

March 8, 2016, AM Session

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

8:35 a.m.  Conflict of Interest Statement

8:45 a.m.  FDA INTRODUCTORY REMARKS

9:00 a.m.  503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS

Quinacrine Hydrochloride

Shrimant Mishra, MD
Medical Officer
Division of Anti-Infective Products
Office of Antimicrobial Products (OAP)
Office of New Drugs (OND), CDER

Keith M. Hull, MD, PhD
Medical Officer
Division of Pulmonary, Allergy, and Rheumatology Products (DPARP)
Office of Drug Evaluation (ODE) II, OND, CDER

Ronald Orleans, MD
Medical Officer
Division of Bone, Reproductive, and Urologic Products (DBRUP)
ODE III, OND, CDER

Susan S. Johnson, PharmD, PhD
Associate Director
ODE IV, OND, CDER

Clarifying Questions from the Committee
FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting
March 8-9, 2016

AGENDA (cont.)

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>10:00 a.m.</td>
<td><strong>BREAK</strong></td>
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<tr>
<td>10:15 a.m.</td>
<td><strong>503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)</strong></td>
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<td><em>Boswellia</em></td>
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<td><em>Janet Maynard, MD, MHS</em> DPARP, ODE II, OND, CDER*</td>
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<td>Clarifying Questions from the Committee</td>
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<td>11:00 a.m.</td>
<td><strong>OPEN PUBLIC HEARING</strong></td>
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<td>11:15 a.m.</td>
<td><strong>COMMITTEE DISCUSSION AND VOTE</strong></td>
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<td>12:00 p.m.</td>
<td><strong>LUNCH</strong></td>
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</table>
AGENDA (cont.)

During the afternoon session, the committee will discuss four additional bulk drug substances nominated for inclusion on the list of bulk drug substances that may be used to compound drugs in accordance with section 503A of the FD&C Act: aloe vera freeze dried 200:1, D-ribose, chondroitin sulfate, and acetyl-L-carnitine.

March 8, 2016, PM Session

1:00 p.m.  **SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS**

* Aloe Vera Freeze Dried 200:1  
  **David Kettl, MD**  
  Lead Medical Officer  
  Division of Dermatology and Dental Products  
  ODE III, OND, CDER

Clarifying Questions from the Committee

**NOMINATOR PRESENTATIONS**  
**Kimberly Kieffer**  
Fagron

Clarifying Questions from the Committee

* D-Ribose  
  **Shari Targum, MD**  
  Lead Medical Officer  
  Division of Cardiovascular and Renal Products  
  ODE I, OND, CDER

  **Janet Maynard, MD, MHS**  
  **Susan S. Johnson, PharmD, PhD**

Clarifying Questions from the Committee

2:00 p.m.  **BREAK**

2:15 p.m.  **SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

* Chondroitin Sulfate  
  **CDR Javier Muniz, MD**  
  Medical Officer  
  Division of Anesthesia, Analgesia, and Addiction Products, ODE II, OND, CDER
Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Acetyl-L-Carnitine

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

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

A.J. Day, PharmD
PCCA

Clarifying Questions from the Committee

3:15 p.m. OPEN PUBLIC HEARING

3:30 p.m. COMMITTEE DISCUSSION AND VOTE

4:30 p.m. ADJOURNMENT
During the morning session, the committee will discuss two categories of drug products, metered dose inhalers and dry powder inhalers, which are nominated for inclusion on the list of demonstrably difficult to compound drugs that may not be used to compound drugs in accordance with sections 503A and 503B of the FD&C Act.

**March 9, 2016, AM Session**

8:30 a.m. Call to Order and Introduction of Committee  
**Padma Gulur, MD**  
Acting Chairperson, PCAC

8:40 a.m. Conflict of Interest Statement  
**Cindy Hong, PharmD**  
Designated Federal Officer, PCAC

8:45 a.m. **FDA PRESENTATIONS—INTRODUCTION OF DEMONSTRABLY DIFFICULT TO COMPOUND AND REVIEW OF CRITERIA**  
**LC DR Cyrus Agarabi, PharmD, RPh, MBA, PhD**  
Senior Regulatory Research Review Officer  
Division of Biotechnology Review and Research II,  
Office of Pharmaceutical Quality (OPQ), CDER

9:15 a.m. **DEMONSTRABLY DIFFICULT TO COMPOUND—FDA PRESENTATIONS**

**Metered Dose Inhalers**  
**Brian Rogers, PhD**  
Chemistry, Manufacturing, and Controls (CMC) Reviewer  
Process Assessment Branch IV  
Division of Process Assessment II  
Office of Process and Facilities OPQ, CDER

Clarifying Questions from the Committee

**NOMINATOR PRESENTATIONS**

Clarifying Questions from the Committee

10:15 a.m. **BREAK**

10:30 a.m. **DEMONSTRABLY DIFFICULT TO COMPOUND—FDA PRESENTATIONS (cont.)**  
**Craig M. Bertha, PhD**  
CMC Lead  
New Drug Products Branch IV  
Division of New Drug Products II  
Office of New Drug Products, OPQ, CDER

Clarifying Questions from the Committee

**NOMINATOR PRESENTATIONS**
Clarifying Questions from the Committee

11:30 a.m. OPEN PUBLIC HEARING

12:00 p.m. COMMITTEE DISCUSSION AND VOTE

1:00 p.m. ADJOURNMENT