During the morning session, the committee will discuss three bulk drug substances nominated for inclusion on the list of bulk drug substances that can be used to compound drugs in accordance with section 503A of the Food, Drug, and Cosmetic Act (FD&C Act): glycolic acid, trichloroacetic acid, and kojic acid.

November 3, 2016, AM Session

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

8:35 a.m. Conflict of Interest Statement
           Cindy Hong, PharmD
           Designated Federal Officer, PCAC

8:40 a.m. FDA INTRODUCTORY REMARKS
           Emily Gebbia, JD
           Senior Advisor
           Office of Compliance, CDER

8:45 a.m. 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS

Glycolic Acid
           Jane Liedtka, MD
           Clinical Reviewer
           Division of Pediatrics and Maternal Health
           Office of Drug Evaluation (ODE) IV
           Office of New Drugs (OND), CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS
           John Voliva, RPh
           International Academy of Compounding Pharmacists (IACP)

Clarifying Questions from the Committee

9:25 a.m. OPEN PUBLIC HEARING

9:35 a.m. COMMITTEE DISCUSSION AND VOTE

9:45 a.m. 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)

Trichloroacetic Acid
           Roselyn E. Epps, MD
           Clinical Reviewer
           Division of Dermatology and Dental Products
           ODE III, OND, CDER

Clarifying Questions from the Committee
**AGENDA (cont.)**

**NOMINATOR PRESENTATIONS**

A.J. Day, PharmD  
Professional Compounding Centers of America (PCCA)

Clarifying Questions from the Committee

10:25 a.m. **OPEN PUBLIC HEARING**

10:35 a.m. **COMMITTEE DISCUSSION AND VOTE**

10:45 a.m. **BREAK**

11:00 a.m. **503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

*Kojic Acid*  
Jonathan Jarow, MD  
Senior Medical Advisor  
Office of the Center Director, CDER

Clarifying Questions from the Committee

**NOMINATOR PRESENTATIONS**  
Tom Wynn, RPh  
Fagron

Clarifying Questions from the Committee

11:40 a.m. **OPEN PUBLIC HEARING**

11:50 a.m. **COMMITTEE DISCUSSION AND VOTE**

12:00 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 drugs in accordance with section 503A of the FD&C Act: diindolylmethane and vasoactive intestinal peptide. The committee will also discuss the following drug products, which were nominated as drug products that present demonstrable difficulties for compounding and that cannot be compounded under sections 503A and 503B of the FD&C Act: drug products that employ transdermal or topical delivery systems (TDS).

November 3, 2016, PM Session

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

Diindolylmethane

Michael Brave, MD
Medical Officer
Division of Oncology Products 1
Office of Hematology and Oncology Products (OHOP)
OND, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

A.J. Day, PharmD
PCCA

Clarifying Questions from the Committee

1:45 p.m. OPEN PUBLIC HEARING

1:55 p.m. COMMITTEE DISCUSSION AND VOTE

2:05 p.m. SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)

Vasoactive Intestinal Peptide

Susan Johnson, PharmD, PhD
Associate Director
Office of Drug Evaluation IV, OND, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Ritchie Shoemaker, MD
Hopkinton Drug Inc.

Clarifying Questions from the Committee

2:50 p.m. OPEN PUBLIC HEARING

3:00 p.m. COMMITTEE DISCUSSION AND VOTE

3:10 p.m. BREAK
AGENDA (cont.)

3:20 p.m. Conflict of Interest Statement

3:25 p.m. DEMONSTRABLY DIFFICULT TO COMPOUND — DRUG PRODUCTS THAT EMPLOY TRANSDERMAL OR TOPICAL DELIVERY SYSTEMS PRESENTATIONS

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Clarifying Questions from the Committee

4:10 p.m. OPEN PUBLIC HEARING

4:20 p.m. COMMITTEE DISCUSSION AND VOTE

4:30 p.m. ADJOURNMENT