During the morning session, the committee will discuss three 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): chrysin, cesium chloride, and sodium dichloroacetate.

Morning Session

8:30 a.m.  Call to Order and Introduction of Committee  
Jürgen Venitz, MD, PhD  
Chairperson, PCAC

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

8:40 a.m.  FDA INTRODUCTORY REMARKS  
Julie Dohm, JD, PhD  
Senior Science Advisor for Compounding CDER

8:45 a.m.  503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS  
Chrysin  
Michael Brave, MD  
Medical Officer  
Division of Oncology Products 1  
Office of Hematology and Oncology Products (OHOP)  
Office of New Drugs (OND), CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS  
Tom Wynn, RPh  
Fagron

Clarifying Questions from the Committee

9:00 a.m.  OPEN PUBLIC HEARING

9:40 a.m.  COMMITTEE DISCUSSION AND VOTE

9:50 a.m.  503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)  
Cesium Chloride  
Michael Brave, MD

Clarifying Questions from the Committee
NOMINATOR PRESENTATIONS

Paul Anderson, ND
American Association of Naturopathic Physicians (AANP)

Clarifying Questions from the Committee

10:35 a.m. OPEN PUBLIC HEARING

10:45 a.m. COMMITTEE DISCUSSION AND VOTE

10:55 a.m. BREAK

11:05 a.m. 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)

Sodium Dichloroacetate

Michael Brave, MD

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Paul Anderson, ND

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, FDA will make a presentation on access to investigational new drugs and then the committee will discuss three 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: pyruvic acid, tea tree oil, and 2,3-Dimercapto-1-propanesulfonic acid (DMPS).

Afternoon Session

1:00 p.m.  **EXPANDED ACCESS TO INVESTIGATIONAL NEW DRUGS**

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

Clarifying Questions from the Committee

1:30 p.m.  **503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

*Pyruvic Acid*

Brenda Carr, MD
Medical Officer
Division of Dermatology and Dental Products
Office of Drug Evaluation III (ODE III), OND, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Tom Wynn, RPh
Fagron

Clarifying Questions from the Committee

2:15 p.m.  **OPEN PUBLIC HEARING**

2:25 p.m.  **COMMITTEE DISCUSSION AND VOTE**

2:35 p.m.  **SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

*Tea Tree Oil*

Hon-Sum Ko, MD
Medical Officer
Division of Dermatology and Dental Products
ODE III, OND, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Alexander Pytlarz, PharmD
NCPA
Clarifying Questions from the Committee

3:20 p.m. OPEN PUBLIC HEARING

3:30 p.m. COMMITTEE DISCUSSION AND VOTE

3:40 p.m. BREAK

3:55 p.m. SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)

2,3-Dimercapto-1-propanesulfonic acid (DMPS)  
Kathy Robie Suh, MD, PhD  
Lead Medical Officer  
Division of Hematology Products, OHOP OND, CDER

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS  
Paul Anderson, ND

Clarifying Questions from the Committee

4:40 p.m. OPEN PUBLIC HEARING

4:50 p.m. COMMITTEE DISCUSSION AND VOTE

5:00 p.m. ADJOURNMENT