AGENDA

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

9:30 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
AGENDA (cont.)

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**

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
National Community Pharmacist Association (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