

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)**

Pharmacy Compounding Advisory Committee (PCAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
June 23, 2016

DRAFT 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

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| 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 | |
| | <i>Chrysin</i> | 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.) | |
| | <i>Cesium Chloride</i> | Michael Brave, MD |
| | Clarifying Questions from the Committee | |

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DRAFT 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**

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DRAFT AGENDA (cont.)

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

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DRAFT AGENDA (cont.)

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**