

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
November 20-21, 2017

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 can be used to compound drug products in accordance with section 503A of the FD&C Act: L-citrulline, pregnenolone, and 7-keto dehydroepiandrosterone (7-keto DHEA).

November 20, 2017, AM 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 Chee, PharmD
Designated Federal Officer, PCAC |
| 8:40 a.m. | FDA INTRODUCTORY REMARKS | Julie Dohm, JD, PhD
Senior Science Advisor for Compounding, CDER
Agency Lead on Compounding, FDA |
| 8:50 a.m. | SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS | |
| | <i>L-citrulline</i> | Susan Johnson, PharmD, PhD
Associate Director
Office of Drug Evaluation IV (ODE IV)
Office of New Drugs (OND), CDER, FDA |
| | Clarifying Questions from the Committee | |
| | NOMINATOR PRESENTATIONS | A.J. Day, PharmD
Professional Compounding Centers of America (PCCA) |
| | Clarifying Questions from the Committee | |
| 9:35 a.m. | OPEN PUBLIC HEARING | |
| 9:45 a.m. | COMMITTEE DISCUSSION AND VOTE | |
| 9:55 a.m. | BREAK | |
| 10:10 a.m. | SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.) | |
| | <i>Pregnenolone</i> | Wafa Harrouk, PhD
Senior Pharmacologist
ODE IV, OND, CDER, FDA |
| | Clarifying Questions from the Committee | |

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DRAFT AGENDA (cont.)

NOMINATOR PRESENTATIONS

A.J. Day, PharmD

Clarifying Questions from the Committee

10:55 a.m. **OPEN PUBLIC HEARING**

11:05 a.m. **COMMITTEE DISCUSSION AND VOTE**

11:15 a.m. **SECTION 503A BULK DRUG SUBSTANCES LIST—FDA PRESENTATIONS (cont.)**

7-Keto dehydroepiandrosterone

Susan Johnson, PharmD, PhD

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

**Tom Wynn, RPh
Fagron**

Clarifying Questions from the Committee

12:00 p.m. **OPEN PUBLIC HEARING**

12:10 p.m. **COMMITTEE DISCUSSION AND VOTE**

12:20 p.m. **LUNCH**

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DRAFT AGENDA (cont.)

During the afternoon session, the committee will discuss three additional bulk drug substances nominated for inclusion on the list of bulk drug substances that can be used to compound drug products in accordance with section 503A of the FD&C Act: astragalus extract 10:1, epigallocatechin gallate (EGCg), and resveratrol.

November 20, 2017, PM Session

1:20 p.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

Astragalus Extract 10:1

Michael Brave, MD
Clinical Reviewer
Division of Oncology Products 1
Office of Hematology and Oncology Products (OHOP)
OND, CDER, FDA

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Tom Wynn, RPh

Clarifying Questions from the Committee

2:05 p.m. **OPEN PUBLIC HEARING**

2:15 p.m. **COMMITTEE DISCUSSION AND VOTE**

2:25 p.m. **BREAK**

2:40 p.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

Epigallocatechin gallate (EGCg)

Susan Johnson, PharmD, PhD

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Kimberly Kieffer
Fagron

Clarifying Questions from the Committee

3:25 p.m. **OPEN PUBLIC HEARING**

3:35 p.m. **COMMITTEE DISCUSSION AND VOTE**

3:45 p.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

Resveratrol

Charles Ganley, MD
Director
ODE IV, OND, CDER, FDA

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting
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DRAFT AGENDA (cont.)

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Jeffery A. Johnson, RPh, MBA, ND, PharmD
Colonel (retired)

National Community Pharmacists Association (NCPA)

Clarifying Questions from the Committee

4:30 p.m. **OPEN PUBLIC HEARING**

4:40 p.m. **COMMITTEE DISCUSSION AND VOTE**

5:00 p.m. **ADJOURNMENT**

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting

November 20-21, 2017

DRAFT AGENDA (cont.)

The committee will 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: liposome drug products and drug products produced using hot melt extrusion.

November 21, 2017

- 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 Chee, PharmD**
Designated Federal Officer, PCAC
- 8:40 a.m. **DEMONSTRABLY DIFFICULT TO COMPOUND LIST– FDA PRESENTATIONS**
Liposome Drug Products **Katherine Tyner, PhD**
Associate Director for Science (Acting)
Office of Pharmaceutical Quality (OPQ), CDER, FDA
- Clarifying Questions from the Committee
- NOMINATOR PRESENTATIONS**
- Clarifying Questions from the Committee
- 9:40 a.m. **OPEN PUBLIC HEARING**
- 9:50 a.m. **COMMITTEE DISCUSSION AND VOTE**
- 10:00 a.m. **BREAK**
- 10:15 a.m. **DEMONSTRABLY DIFFICULT TO COMPOUND LIST– FDA PRESENTATIONS (cont.)**
Drug Products Produced Using Hot Melt Extrusion **Celia N. Cruz, PhD**
Division Director
Division of Product Quality Research
Office of Testing and Research, OPQ, CDER, FDA
- Clarifying Questions from the Committee
- NOMINATOR PRESENTATIONS**
- Clarifying Questions from the Committee
- 11:10 a.m. **OPEN PUBLIC HEARING**
- 11:20 a.m. **COMMITTEE DISCUSSION AND VOTE**

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Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting
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DRAFT AGENDA (cont.)

11:30 a.m. **ADJOURNMENT**

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