

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
May 8-9, 2017

AGENDA

*During the **morning session**, the committee will receive updates on certain issues to follow up on discussions from previous meetings, including quality standards and conditions at certain compounding facilities. In addition, the committee will discuss two 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): nicotinamide adenine dinucleotide and nicotinamide adenine dinucleotide disodium reduced.*

May 8, 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 Hong, 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. | FDA PRESENTATION | |
| | <i>Compounders Under Section 503A of the FD&C Act: Quality Standards and FDA Findings</i> | Sarah Rothman, MPH
Senior Policy Advisor
Office of Unapproved Drugs and Labeling Compliance |
| | Clarifying Questions from the Committee | |
| 9:30 a.m. | SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.) | |
| | <i>Nicotinamide Adenine Dinucleotide</i> | Yen-Ming Chan, PhD
ORISE Fellow
Office of Drug Evaluation (ODE) IV
Office of New Drugs (OND) |
| | Clarifying Questions from the Committee | |
| | NOMINATOR PRESENTATIONS | John Humiston, MD
Fagron |
| | Clarifying Questions from the Committee | |
| 10:15 a.m. | OPEN PUBLIC HEARING | |

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AGENDA (cont.)

10:25 a.m. **COMMITTEE DISCUSSION AND VOTE**

10:35 a.m. **BREAK**

10:50 a.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

Nicotinamide Adenine Dinucleotide
Disodium Reduced

Corrine Kulick, PharmD
Clinical Analyst (Detail)
ODE IV, OND

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Tom Wynn, RPh
Fagron

Clarifying Questions from the Committee

11:35 a.m. **OPEN PUBLIC HEARING**

11:45 a.m. **COMMITTEE DISCUSSION AND VOTE**

11:55 a.m. **LUNCH**

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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 drugs in accordance with section 503A of the FD&C Act: nettle (Urtica dioica) whole plant, ubiquinol, and vanadyl sulfate.

May 8, 2017, PM Session

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

Nettle

Jennifer Shing, PhD

ORISE Fellow

ODE IV, OND

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

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.)**

Ubiquinol

Susan Johnson, PharmD, PhD

Associate Director

ODE IV, OND

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

Tom Wynn, RPh

Fagron

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**

3:25 p.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

Vanadyl Sulfate

Susan Johnson, PharmD, PhD

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AGENDA (cont.)

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**

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

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

During the morning session, the committee will discuss one additional bulk drug substance 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: artemisinin. In addition, the committee will discuss oral solid modified release drug products that employ coated systems, which were nominated for the Difficult to Compound List.

May 9, 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 Hong, PharmD
Designated Federal Officer, PCAC |
| 8:40 a.m. | SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS | |
| | <i>Artemisinin</i> | Wafa Harrouk, PhD
Bindi Nikhar, MD, FAAP
ODE IV, OND |
| | Clarifying Questions from the Committee | |
| | NOMINATOR PRESENTATIONS | |
| | Clarifying Questions from the Committee | |
| 10:00 a.m. | OPEN PUBLIC HEARING | |
| 10:10 a.m. | COMMITTEE DISCUSSION AND VOTE | |
| 10:20 a.m. | BREAK | |
| 10:35 a.m. | DEMONSTRABLY DIFFICULT TO COMPOUND LIST— FDA PRESENTATION | |
| | Oral Solid Modified Release Drug Products that Employ Coated Systems | Muhammad Ashraf, PhD
Office of Testing and Research
Office of Pharmaceutical Quality |
| | Clarifying Questions from the Committee | |
| | NOMINATOR PRESENTATIONS | |
| | Clarifying Questions from the Committee | |
| 11:35 a.m. | OPEN PUBLIC HEARING | |

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AGENDA (cont.)

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

12:00 p.m. **ADJOURNMENT**