

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
September 12, 2018

DRAFT AGENDA

During the morning session, the committee will discuss two 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: alpha lipoic acid and coenzyme Q10.

September 12, 2018, AM Session

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| 8:00 a.m. | Call to Order and Introduction of Committee | Jürgen Venitz, MD, PhD Chairperson, PCAC |
| 8:05 a.m. | Conflict of Interest Statement | Jay Fajiculay, PharmD Acting Designated Federal Officer, PCAC |
| 8:10 a.m. | FDA INTRODUCTORY REMARKS | Julie Dohm, JD, PhD Senior Science Advisor for Compounding, CDER Agency Lead on Compounding, FDA |
| 8:15 a.m. | FDA PRESENTATION Topics will include balancing the criteria for the 503A bulk drug substance evaluation, dietary supplements, and recently issued FDA guidances | Sara Rothman, MPH Senior Policy Advisor Office of Unapproved Drugs and Labeling Compliance Office of Compliance, CDER, FDA |
| | Clarifying Questions from the Committee | |
| 9:15 a.m. | SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS | |
| | <i>Alpha lipoic acid</i> | Michael Brave, MD Medical Officer Division of Oncology Products 1 Office of Hematology and Oncology Products Office of New Drugs (OND), CDER, FDA |
| | Clarifying Questions from the Committee | |
| | NOMINATOR PRESENTATIONS | Arthur Berkson, MD Integrative Medical Center of New Mexico |
| | 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 | |

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DRAFT AGENDA (cont.)

10:30 a.m. **SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**

Coenzyme Q10

Susan Johnson, PharmD, PhD
Associate Director
Office of Drug Evaluation IV (ODE IV)
OND, CDER, FDA

Clarifying Questions from the Committee

NOMINATOR PRESENTATIONS

A.J. Day, PharmD
Professional Compounding Centers of America

Clarifying Questions from the Committee

11:15 a.m. **OPEN PUBLIC HEARING**

11:25 a.m. **COMMITTEE DISCUSSION AND VOTE**

11:35 a.m. **LUNCH**

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DRAFT AGENDA (cont.)

NOMINATOR PRESENTATIONS

Paul Anderson, NMD
Anderson Medical Specialty Associates

Clarifying Questions from the Committee

3:45 p.m.

OPEN PUBLIC HEARING

4:05 p.m.

COMMITTEE DISCUSSION AND VOTE

4:30 p.m.

ADJOURNMENT

DRAFT