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

DRAFT 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

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**	
	Compounders Under Section 503A of the FD&C Act: Quality Standards and FDA Findings	**Sarah Rothman, PharmD** Consumer Safety Officer 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.)**	
	Nicotinamide Adenine Dinucleotide	**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**	

DRAFT 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**	

DRAFT

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting
May 8-9, 2017

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 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**

DRAFT 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**

DRAFT

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting
May 8-9, 2017

DRAFT 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

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**	
	Artemisinin	**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**	

DRAFT

DRAFT AGENDA (cont.)

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

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

DRAFT