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

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

8:00 a.m.	Call to Order and Introduction of Committee	**Allen Vaida, BSc, PharmD** Acting 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**	
	Compounding Updates and Review	**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**	
	Alpha lipoic acid	**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**	

AGENDA (cont.)

10:20 a.m.	**BREAK**	
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**	

FOOD AND DRUG ADMINISTRATION (FDA)
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Pharmacy Compounding Advisory Committee (PCAC) Meeting
September 12, 2018

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: creatine monohydrate, pyridoxal 5 phosphate, and quercetin dihydrate.*

September 12, 2018, PM Session

12:30 p.m.	**SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**	
	Creatine monohydrate	**Susan Johnson, PharmD, PhD**
	Clarifying Questions from the Committee	
	NOMINATOR PRESENTATIONS	**A.J. Day, PharmD**
	Clarifying Questions from the Committee	
1:15 p.m.	**OPEN PUBLIC HEARING**	
1:25 p.m.	**COMMITTEE DISCUSSION AND VOTE**	
1:35 p.m.	**BREAK**	
1:45 p.m.	**SECTION 503A BULK DRUG SUBSTANCES LIST—FDA PRESENTATIONS (cont.)**	
	Pyridoxal 5 phosphate monohydrate	**Susan Johnson, PharmD, PhD**
	Clarifying Questions from the Committee	
	NOMINATOR PRESENTATIONS	**Tom Wynn, RPh** Fagron
	Clarifying Questions from the Committee	
2:30 p.m.	**OPEN PUBLIC HEARING**	
2:40 p.m.	**COMMITTEE DISCUSSION AND VOTE**	
2:50 p.m.	**BREAK**	
3:00 p.m.	**SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**	
	Quercetin dihydrate	**Charles Ganley, MD** Director ODEIV OND, CDER, FDA
	Clarifying Questions from the Committee	

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**	