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

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

8:30 a.m.	Call to Order and Introduction of Committee	**Padma Gulur, MD** Acting 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**	
	L-citrulline	**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.)**	
	Pregnenolone	**Wafa Harrouk, PhD** Senior Pharmacologist ODE IV, OND, CDER, FDA
	Clarifying Questions from the Committee	

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**	

FOOD AND DRUG ADMINISTRATION (FDA)
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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 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

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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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	**Padma Gulur, MD** Acting 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**	

AGENDA (cont.)

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