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
March 8-9, 2016

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 may be used to compound drugs in accordance with section 503A of the Food, Drug, and Cosmetic Act (FD&C Act): quinacrine hydrochloride and boswellia.

March 8, 2016, 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
8:45 a.m.	**FDA INTRODUCTORY REMARKS**	**Frances Gail Bormel, RPh, JD** Director (Acting) Division of Prescription Drugs Office of Unapproved Drugs and Labeling Compliance Office of Compliance, CDER, FDA
9:00 a.m.	**503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS**	
	Quinacrine Hydrochloride	**Shrimant Mishra, MD** Medical Officer Division of Anti-Infective Products Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER
		Keith M. Hull, MD, PhD Medical Officer Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) Office of Drug Evaluation (ODE) II, OND, CDER
		Ronald Orleans, MD Medical Officer Division of Bone, Reproductive, and Urologic Products (DBRUP) ODE III, OND, CDER
		Charles J. Ganley, MD Director ODE IV, OND, CDER
	Clarifying Questions from the Committee	

DRAFT AGENDA (cont.)

	NOMINATOR PRESENTATIONS	**A.J. Day, PharmD** Professional Compounding Centers of American (PCCA)
10:00 a.m.	**BREAK**	
10:15 a.m.	**503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**	
	Boswellia	**Janet Maynard, MD, MHS** Lead Medical Officer DPARP, ODE II, OND, CDER
	Clarifying Questions from the Committee	
	NOMINATOR PRESENTATIONS	**Kimberly Kieffer** Fagron
	Clarifying Questions from the Committee	
11:00 a.m.	**OPEN PUBLIC HEARING**	
11:15 a.m.	**COMMITTEE DISCUSSION AND VOTE**	
12:00 p.m.	**LUNCH**	

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DRAFT AGENDA (cont.)

During the afternoon session, the committee will discuss four additional bulk drug substances nominated for inclusion on the list of bulk drug substances that may be used to compound drugs in accordance with section 503A of the FD&C Act: aloe vera, ribose (d), chondroitin sulfate, and acetyl-L-carnitine.

March 8, 2016, PM Session

1:00 p.m.	**SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS**	
	Aloe Vera 200:1 freeze dried	**David Kettl, MD** Lead Medical Officer Division of Dermatology and Dental Products ODE III, OND, CDER
	Clarifying Questions from the Committee	
	NOMINATOR PRESENTATIONS	**Kimberly Kieffer** Fagron
	Clarifying Questions from the Committee	
	D-Ribose	**Shari Targum, MD** Lead Medical Officer Division of Cardiovascular and Renal Products ODE I, OND, CDER
		Janet Maynard, MD, MHS
		Charles Ganley, MD
	Clarifying Questions from the Committee	
	NOMINATOR PRESENTATIONS	**Kimberly Kieffer** Fagron
	Clarifying Questions from the Committee	
2:00 p.m.	**BREAK**	
2:15 p.m.	**SECTION 503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS (cont.)**	
	Chondroitin Sulfate	**CDR Javier Muniz, MD** Medical Officer Division of Anesthesia, Analgesia, and Addiction Products, ODE II, OND, CDER

DRAFT AGENDA (cont.)

	Clarifying Questions from the Committee	
	NOMINATOR PRESENTATIONS	
	Clarifying Questions from the Committee	
	Acetyl-L-Carnitine	**Kenneth Bergmann, MD** Medical Officer, Division of Neurology Products ODE I, OND, CDER
	Clarifying Questions from the Committee	
	NOMINATOR PRESENTATIONS	**A.J. Day, PharmD** PCCA
	Clarifying Questions from the Committee	
3:15 p.m.	**OPEN PUBLIC HEARING**	
3:30 p.m.	**COMMITTEE DISCUSSION AND VOTE**	
4:30 p.m.	**ADJOURNMENT**	

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DRAFT AGENDA (cont.)

During the morning session, the committee will discuss two categories of drugs, metered dose inhalers and dry powder inhalers, which are nominated for inclusion on the list of demonstrably difficult to compound drugs that may not be used to compound drugs in accordance with sections 503A and 503B of the FD&C Act.

March 9, 2016, AM Session

8:30 a.m.	Call to Order and Introduction of Committee	**Jürgen Venitz, MD, PhD** Chairperson, PCAC
8:40 a.m.	Conflict of Interest Statement	**Cindy Hong, PharmD** Designated Federal Officer, PCAC
8:45 a.m.	**FDA PRESENTATIONS- INTRODUCTION OF DEMONSTRABLY DIFFICULT TO COMPOUND AND REVIEW OF CRITERIA**	
9:15 a.m.	**DEMONSTRABLY DIFFICULT TO COMPOUND – FDA PRESENTATIONS**	
	Metered Dose Inhalers	**Brian Rogers, PhD** Chemistry Manufacturing and Controls (CMC) Reviewer Process Assessment Branch IV Division of Process Assessment II Office of Process and Facilities Office of Pharmaceutical Quality (OPQ), CDER
	Clarifying Questions from the Committee	
	NOMINATOR PRESENTATIONS	
	Clarifying Questions from the Committee	
10:15 a.m.	**BREAK**	
10:30 a.m.	**DEMONSTRABLY DIFFICULT TO COMPOUND – FDA PRESENTATIONS (cont.)**	
	Dry Powder Inhalers	**Craig M. Bertha, PhD** CMC Lead New Drug Products Branch IV Division of New Drug Products II Office of New Drug Products, OPQ, CDER
	Clarifying Questions from the Committee	
	NOMINATOR PRESENTATIONS	

DRAFT AGENDA (cont.)

	Clarifying Questions from the Committee
11:30 a.m.	**OPEN PUBLIC HEARING**
12:00 a.m.	**COMMITTEE DISCUSSION AND VOTE**
1:00 p.m.	**ADJOURNMENT**