

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
October 27-28, 2015

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): methylsulfonylmethane, and curcumin.*

October 27, 2015, AM Session

10:00 a.m.	Call to Order and Introduction of Committee	Jürgen Venitz, MD, PhD Chairperson, PCAC
10:05 a.m.	Conflict of Interest Statement	Cindy Hong, PharmD Acting Designated Federal Officer, PCAC
10:15 a.m.	FDA INTRODUCTORY REMARKS	Jane A. Axelrad, JD Associate Director for Policy, CDER and Agency Lead on Compounding
	Clarifying Questions	
10:45 a.m.	FDA PRESENTATIONS	
	Dietary Supplements as Bulk Drug Substances	John Brad Pace, JD Chief Health Fraud Branch Division of Non-Prescription Drugs & Health Fraud Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER
	Botanical Evaluation as Active Pharmaceutical Ingredients	Sau (Larry) Lee, PhD Acting Associate Director for Science Acting Team Leader for Office of Pharmaceutical Quality (OPQ) Botanical Review Team, Immediate Office, OPQ, CDER
	Clarifying Questions from the Committee	
11:15 a.m.	SECTION 503A BULK DRUG SUBSTANCES LIST FDA PRESENTATIONS	
	<i>Methylsulfonylmethane</i>	Anjelina Pokrovnichka, MD Medical Officer Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE II), Office of New Drugs (OND), CDER

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October 27-28, 2015

AGENDA (cont.)

Clarifying Questions from the Committee

SECTION 503A BULK DRUG SUBSTANCES LIST
FDA PRESENTATIONS (cont.)

Curcumin

Sandra Casak, MD
Medical Officer
Division of Oncology Products (DOP) 2
Office of Hematology and Oncology Products
(OHOP), OND, CDER

Clarifying Questions from the Committee

12:00 p.m. **NOMINATOR PRESENTATIONS**

Methylsulfonylmethane

A.J. Day, PharmD
Professional Compounding Centers of American
(PCCA)

Christopher L. Gruber, PharmD
Fagron

12:30 p.m. **LUNCH**

FOOD AND DRUG ADMINISTRATION (FDA)
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Pharmacy Compounding Advisory Committee (PCAC) Meeting

October 27-28, 2015

AGENDA (cont.)

During the afternoon session, the committee will continue discussing the two bulk drug substances discussed in the morning and discuss three 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: germanium sesquioxide, rubidium chloride, and deoxy-D-glucose.

October 27, 2015, PM Session

1:30 p.m. **OPEN PUBLIC HEARING**

1:45 p.m. **COMMITTEE DISCUSSION AND VOTE**

2:15 p.m. **SECTION 503A BULK DRUG SUBSTANCES LIST
FDA PRESENTATIONS**

Germanium Sesquioxide

Sanjeeve Balasubramaniam, MD, MPH
Medical Officer
DOP 1, OHOP, OND, CDER

Clarifying Questions from the Committee

Rubidium Chloride

Sanjeeve Balasubramaniam, MD, MPH

Clarifying Questions from the Committee

Deoxy-D-Glucose

Sanjeeve Balasubramaniam, MD, MPH

Jeffrey Murray, MD
Deputy Division Director
Division of Antiviral Products (DAVP)
Office of Antimicrobial Products (OAP), OND, CDER

Clarifying Questions from the Committee

3:15 p.m. **BREAK**

3:30 p.m. **NOMINATOR PRESENTATIONS**

Deoxy-D-Glucose

A.J. Day, PharmD
PCCA

Richard B Moon PharmD, RPh, FIACP
National Community Pharmacists Association (NCPA)

4:15 p.m. **OPEN PUBLIC HEARING**

4:30 p.m. **COMMITTEE DISCUSSION AND VOTE**

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting
October 27-28, 2015

AGENDA (cont.)

5:30 p.m. **ADJOURNMENT**

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting

October 27-28, 2015

AGENDA (cont.)

During the morning session, the committee will discuss three 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: alanyl-L-glutamine, glutaraldehyde, and glycyrrhizin.

October 28, 2015, 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 Acting Designated Federal Officer, PCAC
8:45 a.m.	SECTION 503A BULK DRUG SUBSTANCES LIST FDA PRESENTATIONS	
	<i>Alanyl-L-Glutamine</i>	Joyce Korvick, MD, MPH Deputy Director for Safety Division of Gastroenterology and Inborn Errors Products (DGIEP), ODE III, OND, CDER
	Clarifying Questions from the Committee	
	<i>Glutaraldehyde</i>	Hon Sum Ko, MD Medical Officer Division of Dermatology and Dental Products (DDDP), ODE III, OND, CDER
	Clarifying Questions from the Committee	
	<i>Glycyrrhizin</i>	Sarah Connelly, MD Medical Officer DAVP, OAP, OND, CDER
	Clarifying Questions from the Committee	
10:00 a.m.	NOMINATOR PRESENTATIONS	
10:45 a.m.	BREAK	
11:00 a.m.	OPEN PUBLIC HEARING	
11:15 a.m.	COMMITTEE DISCUSSION AND VOTE	
12:00 p.m.	LUNCH	

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting
October 27-28, 2015

AGENDA (cont.)

During the afternoon session, the committee will discuss domperidone, which is 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.

October 28, 2015, PM Session

1:00 p.m. **SECTION 503A BULK DRUG SUBSTANCES LIST**
FDA PRESENTATIONS

Domperidone

Catherine Sewell, MD, MPH
Medical Officer
Division of Bone, Reproductive and Urologic
Products (DBRUP), ODE III, OND, CDER

Leslie McKinney, PhD
Pharmacology/Toxicology Reviewer
DBRUP, ODE III, OND, CDER

Anil Rajpal, MD
Lead Medical Officer
DGIEP, ODE III, OND, CDER

Clarifying Questions from the Committee

2:00 p.m. **NOMINATOR PRESENTATIONS**

Domperidone

A.J. Day, PharmD
PCCA

Richard B. Moon PharmD, RPh, FIACP
NCPA

2:45 p.m. **OPEN PUBLIC HEARING**

3:30 p.m. **BREAK**

3:45 p.m. **COMMITTEE DISCUSSION AND VOTE**

4:45 p.m. **ADJOURNMENT**