

**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

**AGENDA**

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*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.*

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**March 8, 2016, AM Session**

8:30 a.m.	Call to Order and Introduction of Committee	<b>Padma Gulur, MD</b> Acting Chairperson, PCAC
8:35 a.m.	Conflict of Interest Statement	<b>Cindy Hong, PharmD</b> Designated Federal Officer, PCAC
8:45 a.m.	<b>FDA INTRODUCTORY REMARKS</b>	<b>Frances Gail Bormel, RPh, JD</b> Director (Acting) Division of Prescription Drugs Office of Unapproved Drugs and Labeling Compliance Office of Compliance, CDER
9:00 a.m.	<b>503A BULK DRUG SUBSTANCES LIST – FDA PRESENTATIONS</b>	
	<i>Quinacrine Hydrochloride</i>	<b>Shrimant Mishra, MD</b> Medical Officer Division of Anti-Infective Products Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER
		<b>Keith M. Hull, MD, PhD</b> Medical Officer Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) Office of Drug Evaluation (ODE) II, OND, CDER
		<b>Ronald Orleans, MD</b> Medical Officer Division of Bone, Reproductive, and Urologic Products (DBRUP) ODE III, OND, CDER
		<b>Susan S. Johnson, PharmD, PhD</b> Associate Director ODE IV, OND, CDER

Clarifying Questions from the Committee

**FOOD AND DRUG ADMINISTRATION (FDA)**  
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**AGENDA (cont.)**

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**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**

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

March 8-9, 2016

**AGENDA (cont.)**

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*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 freeze dried 200:1, D-ribose, chondroitin sulfate, and acetyl-L-carnitine.*

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**March 8, 2016, PM Session**

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

*Aloe Vera Freeze Dried 200:1*

**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**

**Susan S. Johnson, PharmD, PhD**

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

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

*Pharmacy Compounding Advisory Committee (PCAC) Meeting*  
March 8-9, 2016

**AGENDA (cont.)**

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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**

**FOOD AND DRUG ADMINISTRATION (FDA)**  
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**AGENDA (cont.)**

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*During the morning session, the committee will discuss two categories of drug products, 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.*

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**March 9, 2016, AM Session**

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|------------|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8:30 a.m.  | Call to Order and Introduction of Committee                                                             | <b>Padma Gulur, MD</b><br>Acting Chairperson, PCAC                                                                                                                                                         |
| 8:40 a.m.  | Conflict of Interest Statement                                                                          | <b>Cindy Hong, PharmD</b><br>Designated Federal Officer, PCAC                                                                                                                                              |
| 8:45 a.m.  | <b>FDA PRESENTATIONS- INTRODUCTION OF DEMONSTRABLY DIFFICULT TO COMPOUND AND REVIEW OF CRITERIA</b>     | <b>LCDR Cyrus Agarabi, PharmD, RPh, MBA, PhD</b> Senior Regulatory Research Review Officer<br>Division of Biotechnology Review and Research II,<br>Office of Pharmaceutical Quality (OPQ), CDER            |
| 9:15 a.m.  | <b>DEMONSTRABLY DIFFICULT TO COMPOUND – FDA PRESENTATIONS</b><br><br><i>Metered Dose Inhalers</i>       | <b>Brian Rogers, PhD</b><br>Chemistry, Manufacturing, and Controls (CMC)<br>Reviewer<br>Process Assessment Branch IV<br>Division of Process Assessment II<br>Office of Process and Facilities<br>OPQ, CDER |
|            | Clarifying Questions from the Committee                                                                 |                                                                                                                                                                                                            |
|            | <b>NOMINATOR PRESENTATIONS</b>                                                                          |                                                                                                                                                                                                            |
|            | Clarifying Questions from the Committee                                                                 |                                                                                                                                                                                                            |
| 10:15 a.m. | <b>BREAK</b>                                                                                            |                                                                                                                                                                                                            |
| 10:30 a.m. | <b>DEMONSTRABLY DIFFICULT TO COMPOUND – FDA PRESENTATIONS (cont.)</b><br><br><i>Dry Powder Inhalers</i> | <b>Craig M. Bertha, PhD</b><br>CMC Lead<br>New Drug Products Branch IV<br>Division of New Drug Products II<br>Office of New Drug Products, OPQ, CDER                                                       |
|            | Clarifying Questions from the Committee                                                                 |                                                                                                                                                                                                            |
|            | <b>NOMINATOR PRESENTATIONS</b>                                                                          |                                                                                                                                                                                                            |

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**AGENDA (cont.)**

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Clarifying Questions from the Committee

11:30 a.m.    **OPEN PUBLIC HEARING**

12:00 p.m.    **COMMITTEE DISCUSSION AND VOTE**

1:00 p.m.    **ADJOURNMENT**