

## Excipient Monographs 2 Expert Committee (EM 2 EC) Meeting Wednesday – Thursday, December 6 – 7, 2017 Briggs Parker, Wiley, Marshall Rooms USP Headquarters, Rockville, Maryland

# Agenda-Draft

#### Goals and Objectives of the Meeting

- Review FY17 Two Year EC Accomplishments
- Review and Update EM2 Work Plan
- Monograph Updates
- Discuss PDG Reforms
- Expert Panel Updates
- Element Specific Chapter Update
- General Chapters Update
- Bilateral Progress and Updates

#### Attendees

Attendee list provided on the day of the meeting

# Day 1 Wednesday, December 6, 2017

# CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS

8:30 a.m. END OF CL		<ul> <li>Procedural Matters and Standard of Conduct (Informational)</li> <li>a. Call Meeting to Order</li> <li>b. Establish Quorum</li> <li>c. Identification of Observers and Confidential Information</li> <li>d. Conflicts of Interest</li> <li>ED SESSION</li> </ul>	Dr. Houck
8:45 a.m.	2.	<ul> <li>Opening and Procedural Matters</li> <li>(Informational &amp; Decision-making)</li> <li>a. Meetings Center Announcements</li> <li>b. Welcome</li> <li>c. Introductions</li> <li>d. Approval of Previous Meeting Minutes (Nov 7)</li> <li>e. Approval of the Agenda</li> </ul>	Ms. Hawkins Dr. Houck All Dr. Houck Dr. Houck
9:00 a.m.	3.	<ul> <li>FY17 Two Year EM2 EC Accomplishments</li> <li>a. PDG sign-offs</li> <li>b. Stage 6 and Stage 4 publications</li> <li>c. PF publications and Approved Standards – USP39-NF 34 1S, USP39-NF34 2S, USP40-NF35</li> </ul>	Ms. Sheehan/Dr. Liu
9:20 a.m.	4.	<b>Review and Update EM2 usp.org Work Plan</b> a. FY18 Work Plan prioritization	Ms. Sheehan/Dr. Liu



9:40 a.m.	<ul> <li><b>5.</b> Review USP-NF Standard Setting Process         <ul> <li>a. Review Reference Standards and RS Candidate Evaluation Package (RSCEP)</li> <li>b. Review Balloting Responsibilities</li> </ul> </li> </ul>
10:20 a.m.	Break
10:35 a.m.	<ul> <li>6. Monograph Updates <ul> <li>a. Newly added PDG Monographs</li> <li>SC K Members/Dr. Liu</li> <li>i. Myristyl Myristate</li> <li>Expected Outcome: Review updated draft proposal</li> <li>ii. Polysorbate 65</li> <li>Dr. Sun</li> <li>Expected Outcome: Review updated draft proposal</li> <li>And discuss DEG/EG testing results in polysorbates</li> <li>iii. Sodium Cetyl Sulfate</li> <li>Expected Outcome: Discuss JP's comments and discuss path forward</li> <li>iv. Isostearyl Alcohol</li> <li>Expected Outcome: Review JP's first draft proposal and discuss path forward</li> <li>v. Calcium Silicate</li> <li>Mr. Bluj</li> <li>Expected Outcome: Review updated draft proposal</li> </ul> </li> </ul>
12:00 p.m.	Lunch (Group Photo)
1:00 p.m.	7. Discuss PDG ReformsDr. Moorea. Update and Workstream ImplementationDr. Mooreb. Impact on EM2 Workplan and USPDr. Moore
2:15 p.m.	Break
2:30 p.m.	<ul> <li>8. Monograph Updates (continued)         <ul> <li>a. E-08 Carmellose Sodium (SC D)</li> <li>b. Assay and Viscosity</li> <li><u>Expected Outcome:</u> Prepare Stage 1 draft to PDG</li> <li>b. E-22/24/62 Lastage Aphydroup/Manaphydrata/</li> </ul> </li> </ul>
	<ul> <li>b. E-23/24/63 Lactose, Anhydrous/Monohydrate/ for Inhalation (SC I)</li> <li>Dr. Tu</li> <li>i. Assay &amp; Impurity</li> </ul>
	Expected Outcome:       Prepare Stage 1 draft to PDG         c. E-33/34/35 Saccharin/Sodium/Calcium (SC I)       Dr. Osterberg/Dr. Liu         i. Assay/Impurity       Expected Outcome:         Status update and discussion
	on impurity specs d. E-28/29 Petrolatum/White (SC K) Mr. Yasika i. Polycyclic aromatic hydrocarbons (PAHs) <u>Expected Outcome:</u> Prepare Stage 2 draft to PDG



	<ul> <li>e. E-17/18 Ethylcellulose/Hydroxyethylcellulose (</li> <li>Assay</li> <li><u>Expected Outcome:</u> Discuss data with and with</li> </ul>	· · · ·		
4:00 p.m.	9. Excipient Impurities Joint Subcommittee (EM1 a. Stimuli article	& EM2) All		
5:00 p.m.	Adjourn for the Day			
5:15 p.m.	Transportation Departs for Hotel			
6:00 p.m.	Dinner at:			
	<b>Trapezaria</b> 11 N. Washington St. Rockville, MD 20850			
Day 2 Thursday, I	December 7, 2017			
8:30 a.m.	<b>10. Expert Panel Updates</b> a. GlycerinDr. Cb. Talc Methods	Cabelka/Ms. Rucker/Dr. Liu Ms. Pier/Dr. Liu		
9:30 a.m.	<ul> <li>11. Monograph Updates (continued) <ul> <li>a. E-30 Polyethylene Glycol (SC K)</li> <li>i. ID by IR</li> <li><u>Expected Outcome:</u> Review final proposal</li> <li>ii. Aldehydes</li> <li><u>Expected Outcome:</u> Discuss path forward ovalidation and specifications</li> </ul> </li> <li>b. E-36 Silicon Dioxide (SC E) <ul> <li>i. Round Robin Study</li> <li>ii. USP Lab Reports</li> <li><u>Expected Outcome:</u> Provide update on Roand review lab reports</li> </ul> </li> </ul>	on Dr. Liu/Dr. Moore		
10:15 a.m.	Break			
10:30 a.m.	<ul> <li>12. Monograph Updates (continued) <ul> <li>a. E-16/32/54 – Crospovidone/ Povidone/ Copovidone (SC G)</li> <li>i. GPC method for Assay &amp; Impurity</li> <li>ii. Expected Outcome: Prepare Stage 1 draft</li> </ul> </li> </ul>	Dr. Wu/Ms. Tordik/Dr. Tu		
		Empowering a healthy tomorrow		



	<ul> <li>iii. Potential revision for lead and formion test</li> <li><u>Expected Outcome</u>: Discuss revision from Sponsor</li> <li>b. E-44 Stearic Acid</li> <li><u>Expected Outcome</u>: Discuss JP fatty composition test results</li> </ul>	n proposal Dr. Maus
11:15 a.m.	<ul><li>13. Element Specific Chapter Update</li><li>a. Elemental Specific Chapters</li></ul>	USP Staff
12:00 p.m.	Lunch	
1:00 p.m.	<ul> <li>14. General Chapters Revision Update <ul> <li>a. G-02 Bulk Density and Tapped Density</li> <li>b. G-05 Powder Flow</li> <li>c. G-19 Density of Solids</li> </ul> </li> </ul>	Dr. Liu
1:45 p.m.	<ul> <li>15. Bilateral Progress and Updates <ul> <li>a. Japanese Pharmacopeia</li> <li>b. Chinese Pharmacopeia</li> <li>c. International Meeting of the World Pharmad. ICH</li> </ul> </li> </ul>	Dr. Moore/Dr. Kameyama/Dr. Liu macopeias
2:45 p.m.	16. Meeting Wrap-Up and Action Items	Mr. Lew
3:00 p.m.	Adjourn	

# 3:15 p.m. Transportation Departs for Hotel/Airport