**2020 – 2025 Over the Counter Methods and Approaches Expert Committee**

**(OTC MA EC)**

**Tuesday, April 6, 2021**

**1:00 p.m. – 3:30 p.m.**

**Teleconference**

**Agenda**

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**Goals and Anticipated Outcomes**

* FDA Presentation
* Work Plan updates

**Attendees**

**Expert Committee Members**

1. Raphael Ornaf, Chair
2. Carmen Gonzalez, Vice Chair
3. Kylen Whitaker
4. Gregory Webster
5. Robert Buice
6. Tim Gilmor
7. Paul Fackler
8. Doug Durham
9. Donna Seibert

**Expert Committee Observers**

1. Reinhard Walter
2. Mike Wisser
3. Mary Seibel
4. Gail Reed

**Government Liaisons**

Moshe Honick, FDA; Douglas Kirkpatrick, FDA; Tara Gooen Bizjak, FDA

**USP Staff**

Domenick Vicchio, Ed Gump, Edith Chang, Heather Joyce, James Austgen

1:00 p.m. **1.** **Opening, Procedural, and Administrative Matters**

* 1. Welcome, Opening Remarks, Introduction Dr. Ornaf
	2. Roll Call Dr. Austgen
	3. Establish quorum Dr. Austgen
	4. Conflicts of Interest, Confidentiality, Code of Ethics

and Recording Policy Dr. Austgen

* 1. Approval of Agenda All
	2. Approval of Previous Minutes All

1:10 p.m. **2.** **FDA Feedback for OTC Standards**

* 1. Presentation Dr. Honick
	2. DiscussionAll

2:300 p.m. **3.** **Work Plan Updates**

1. Plan Summary Dr. Chang
2. Expert Committee action plan All

3:25 p.m. **4.** **Meeting Wrap-up and Action Items** Dr. Austgen

3:30 p.m. **5.** **Adjourn**