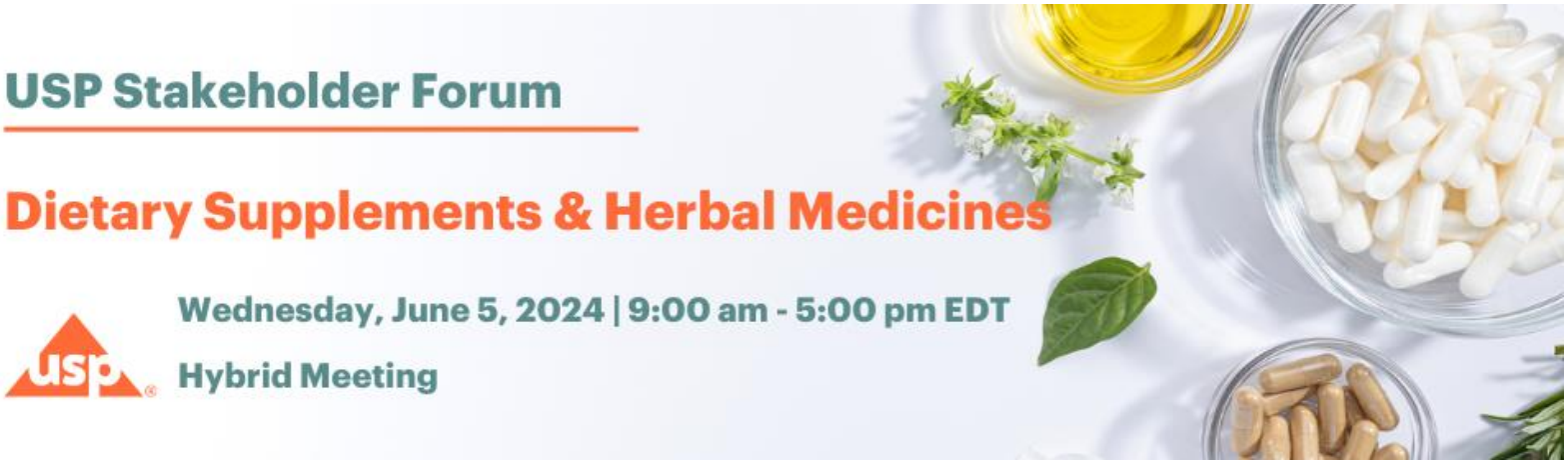


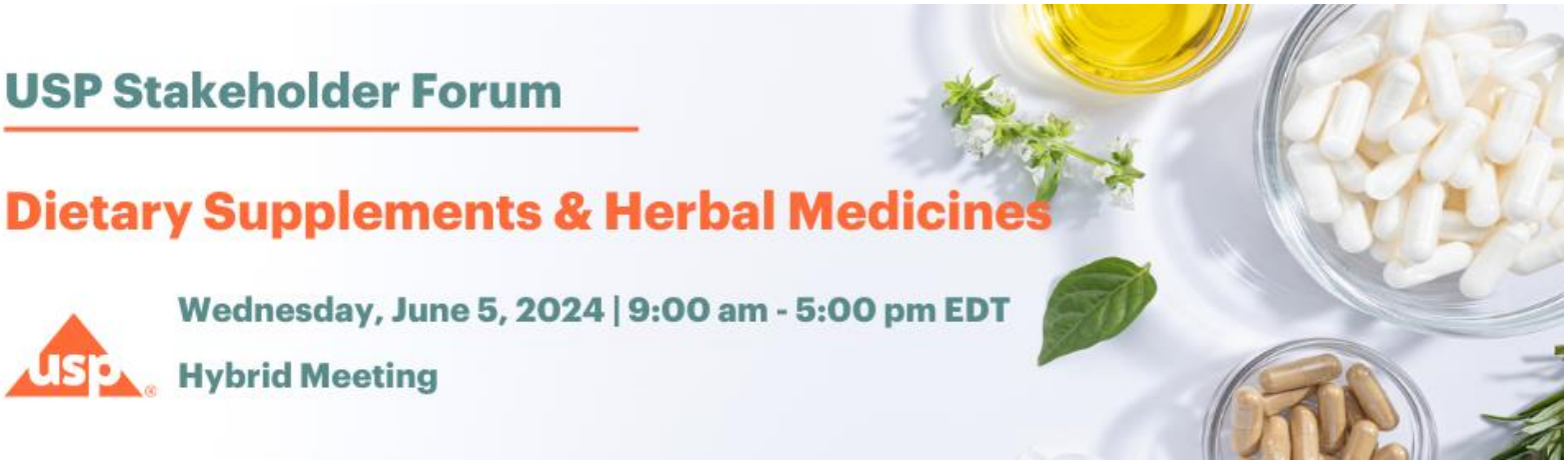
USP Rockville Headquarters | 12601 Twinbrook Parkway | Rockville, MD 20852

Draft Agenda (May 22, 2024)

Event Moderator: Duffy Mackay, USP Dietary Supplements & Herbal Medicines Stakeholder Forum Planning Committee Chair and Senior Vice President Dietary Supplements, Consumer Healthcare Products Association

8:30 a.m. – 9:00 a.m.	**Registration, Coffee, and Tea Services**
9:00 a.m. – 9:05 a.m.	**Welcome and Logistics** Speaker: Jacqueline D. Starkes, Program Manager I USP
9:05 a.m. – 9:10 a.m.	**Introduction and Objectives for Today's Dietary Supplements & Herbal Medicines Stakeholder Forum** Speaker: Duffy Mackay, USP Dietary Supplements & Herbal Medicines Stakeholder Forum Planning Committee, Chair
9:10 a.m. – 10:10 a.m.	**USP Updates: Past, Present, and Future Activities** **Expected Outcome:** Provide an understanding of the importance of stakeholder engagement for USP, along with an update on recent and upcoming USP activities. **Moderator:** James Griffiths, Senior Vice President International & Scientific Affairs | Council for Responsible Nutrition a. Standard Development Activities Overview, Kit Goldman | USP b. Monograph Compliance vs. USP Verification Program, Seong Jae Yoo | USP c. Admission Evaluation for Ingredients, Nadeem Akhtar | USP **Facilitated Panel Discussion** **Moderator:** James Griffiths, Senior Vice President International & Scientific Affairs | Council for Responsible Nutrition
10:10 a.m. –10:20 a.m.	**Chewable Gels (aka Gummies)** **Expected Outcome:** Discuss new insights into the manufacturing processes for gummies, their impact on quality, and the challenges associated with testing and stability. **Moderator:** Mohamed Koroma, Director R & D | Pharmavite
10:20 a.m. – 10:35 a.m.	**Break**
10:35 a.m. – 11: 30 a.m.	**Chewable Gels (aka Gummies) Continued** a. Formulator Perspective: Manufacturing Processes, Ed Shneyvas, USP Non-Botanical Dietary Supplements EC | Member b. Industry Perspective: Impact on Quality, Katie Banaszewski, Senior Director of Quality | NOW c. Contract Labs Perspective: Challenges Associated with Testing, Grace Bandong | Eurofins d. USP Perspectives: Natalia Davydova, Principal Scientist | USP

	Facilitated Panel Discussion **Moderator:** Mohamed Koroma, Director R & D | Pharmavite
11:30 a.m. – 12:30 p.m.	**Establishing Specifications for the Identification of Botanicals** **Expected Outcome:** Discuss current challenges, compendial perspectives, and the need for identity specifications in new USP Standards. **Moderator:** Holly Johnson, Chief Science Officer | American Herbal Products Association a. USP Perspective: Robin Marles, Chair of the Botanical Dietary Supplements and Herbal Medicines EC | USP b. Regulatory Perspective: Haijing Hu | U.S. FDA c. Industry Perspective: Elan Sudberg | Alkemist
	Facilitated Panel Discussion **Moderator:** Holly Johnson, Chief Science Officer | American Herbal Products Association
12:30 p.m. – 1:30 p.m.	**Lunch**
1:30 p.m. – 2:45 p.m.	**Unique Challenges Related to Evaluating Quality of Dietary Supplements Containing Probiotics** **Expected Outcome:** Discuss the FDA's perspectives on the USP approach to probiotic standards and share the industry's challenges in maintaining the quality of supplements containing probiotics. **Moderator:** Bill Turney, Senior Director Regulatory Affairs | Kerry Foods a. FDA's Perspectives on Probiotics: Betsy Jean Yakes | U.S. FDA b. DNA-based Methods for Strain-Specific Identification and Enumeration of Probiotics: Hanan Shehata | Purity-IQ c. Probiotic Finished Dosage Forms Quality: ID, Enumeration, Shelf Life, Overages, Marie-Eve Boyte | Probiotic Expert panel & Nutra Pharma Consulting Services d. USP's Perspectives: Binu Koshy, Team Lead, Senior Scientist II | USP
	Facilitated Panel Discussion **Moderator:** Bill Turney, Senior Director Regulatory Affairs | Kerry Foods
2:45 p.m. – 3:00 p.m.	**Break**
3:00 p.m. – 4:00 p.m.	**Fireside Chat: How Can We Move the Needle: Common GMP Warning Letters - Failure To Meet Specifications** **Expected Outcome:** Discuss current observations from FDA GMP inspections. **Moderator:** Robert Durkin, Co-Chair of the Food & Drug Practice | Arnold Golden Gregory, LLP Arnold a. Tyler Daniels, Senior Scientist | Thorne b. Jennifer Ahearn, CEO | GMPACT
	Facilitated Panel Discussion **Moderator:** Robert Durkin, Co-Chair of the Food & Drug Practice | Arnold Golden Gregory, LLP



4:00 p.m. – 4:50 p.m.	**Open Mic: An Invitation to Bring Your Topics to The Agenda to Discuss** **Moderator:** Duffy Mackay, Dietary Supplements & Herbal Medicines Stakeholder Forum Planning Committee, Chair
4:50 p.m. – 4: 58 p.m.	**Next Steps/Closing Remarks/Slido Survey** **Moderator:** Duffy Mackay, Dietary Supplements & Herbal Medicines Stakeholder Forum Planning Committee, Chair
5:00 p.m.	**Adjourn**