

Facilitating Generic Product Development Through Product-Specific Guidances (PSGs)

April 25, 2024, 1:00 – 4:00 pm EDT

Welcome (5 min)	<p>Welcome</p> <p>Nora Lim, PharmD, BCPS, <i>Lieutenant Commander</i>, United States Public Health Service <i>Pharmacist</i></p> <p>Small Business and Industry Assistance (SBIA) Division of Drug Information (DDI) Office of Communications (OCOMM) Center for Drug Evaluation and Research (CDER) U.S. Food and Drug Administration (FDA)</p>	1:00 - 1:05 pm
Talk 1 (25 min)	<p>PSG Program: Updates and Overview of Available Resources</p> <p>Joseph Kotsybar, Pharm.D. <i>Regulatory Health Project Manager</i></p> <p>Office of Research and Standards (ORS) Office of Generic Drugs (OGD) CDER FDA</p>	1:05 - 1:30 pm
Talk 2 (15 min)	<p>Beyond General Guidance: Tailored PSG Recommendations for Immediate Release Oral Drug Products</p> <p>Qi Zhang, Ph.D. <i>Lead Pharmacologist</i></p> <p>Division of Therapeutic Performance II (DTP II) ORS OGD CDER FDA</p>	1:30 - 1:45 pm
Talk 3 (15 min)	<p>Development of Generic Drug Products Under Suitability Petition</p> <p>Heather Boyce, Ph.D. <i>Lead Pharmacokineticist</i></p> <p>DTP II ORS OGD CDER FDA</p>	1:45 – 2:00 pm
Talk 4 (15 min)	<p>Device and User Interface Assessment Recommendations in Drug-Device Combination Product PSGs</p> <p>Karthika Natarajan, Ph.D. <i>Staff Fellow</i></p> <p>DTP I ORS OGD CDER FDA</p>	2:00 – 2:15 pm
Talk 5 (15 min)	<p>Consideration Factors for Study Population Selection in Bioequivalence Studies with Pharmacokinetic Endpoints</p> <p>Jihong Shon, M.D., Ph.D. <i>Senior Staff Fellow</i></p> <p>DTP II ORS OGD CDER FDA</p>	2:15 – 2:30 pm
Talk 6 (10 min)	<p>FDA Dissolution Methods and Navigating the Dissolution Database</p> <p>Leah W. Falade, Ph.D. <i>Senior Pharmacologist</i></p> <p>Office of Product Quality Assessment II (OPQA II) Office of Pharmaceutical Quality (OPQ) CDER FDA</p>	2:30 – 2:40 pm

Panel Discussion (40 min)	Moderator: Joseph Kotsybar, Pharm.D., <i>Regulatory Health Project Manager</i> , ORS OGD CDER FDA	2:40 – 3:20 pm
	Panelists:	
	<ul style="list-style-type: none"> • Dave Coppersmith, J.D., Regulatory Counsel, Division of Drug Policy, Office of Generic Drug Policy, OGD, CDER • Utpal Munshi, Ph.D., Division Director, Division of Bioequivalence I, Office of Bioequivalence, OGD, CDER • Markham Luke, M.D., Ph.D., Division Director, DTP I, ORS, OGD, CDER • Myong-Jin Kim, Pharm. D., Division Director, DTP II, ORS, OGD, CDER • Liang Zhao, Ph.D., Division Director, Division of Quantitative Methods and Modeling, ORS, OGD, CDER • Lei Zhang, Ph.D., Deputy Director, ORS, OGD, CDER • Leah Falade, Ph.D., OPQA II, OPQ, CDER 	
Speaker Q&A (35 min)	Moderator: Forest “Ray” Ford, Jr.	3:20 – 3:55 pm
	Speakers:	
	<ul style="list-style-type: none"> • Joseph Kotsybar • Qi Zhang • Heather Boyce • Karthika Natarajan • Jihong Shon • Leah Falade 	
Closing Remarks (5 min)	Closing Remarks Robert Lionberger, Ph.D. <i>Director</i> , ORS OGD CDER FDA	3:55 – 4:00 pm