CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

WEBINARS

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

April 25, 2024, 1:00 – 4:00 pm EDT

Welcome (5 min)	**Welcome** Nora Lim, PharmD, BCPS, *Lieutenant Commander*, United States Public Health Service *Pharmacist* 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)	1:00 - 1:05 pm
Talk 1 (25 min)	**PSG Program: Updates and Overview of Available Resources** Joseph Kotsybar, Pharm.D. *Regulatory Health Project Manager* Office of Research and Standard (ORS) | Office of Generic Drugs (OGD) | CDER | FDA	1:05 - 1:30 pm
Talk 2 (15 min)	**Beyond General Guidance: Tailored PSG Recommendations for Immediate Release Oral Drug Products** Qi Zhang, Ph.D. *Lead Pharmacologist* Division of Therapeutic Performance II (DTP II) | ORS | OGD | CDER | FDA	1:30 - 1:45 pm
Talk 3 (10 min)	**Biopharmaceutics Classification System-Based Waiver Options in PSGs** Yi Zhang, Ph.D. *Regulatory Officer* DTP II | ORS | OGD | CDER | FDA	1:45 – 1:55 pm
Talk 4 (15 min)	**Development of Generic Drug Products Under Suitability Petition** Heather Boyce, Ph.D. *Lead Pharmacokineticist* DTP II | ORS | OGD | CDER | FDA	1:55 – 2:10 pm
Talk 5 (15 min)	**Device and User Interface Assessment Recommendations in Drug-Device Combination Product PSGs** Karthika Natarajan, Ph.D. Staff Fellow DTP I | ORS | OGD | CDER | FDA	2:10 – 2:25 pm
Talk 6 (15 min)	**Consideration Factors for Study Population Selection in Bioequivalence Studies With Pharmacokinetic Endpoints** Jihong Shon, Ph.D. Senior Staff Fellow DTP II | ORS | OGD | CDER | FDA	2:25 – 2:40 pm
Talk 7 (10 min)	**FDA Dissolution Methods and Navigating the Dissolution Database** Leah W. Falade, Ph.D. Senior Pharmacologist Office of Product Quality Assessment II (OPQA II) | Office of Pharmaceutical Quality (OPQ)| CDER | FDA	2:40 – 2:50 pm

Panel Discussion (30 min)	**Moderator:** Joseph Kotsybar, Pharm.D.**,** *Regulatory Health Project Manager,* ORS | OGD | CDER | FDA **Panelists:** • 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	2:50 – 3:20 pm
Speaker Q&A (35 min)	**Moderator:** Forest "Ray" Ford, Jr. **Speakers:** • Joseph Kotsybar • Yi Zhang • Qi Zhang • Heather Boyce • Karthika Natarajan • Jihong Shon • Leah Falade	3:20 – 3:55 pm
Closing Remarks (5 min)	**Closing Remarks** Robert Lionberger, Ph.D. *Director*, ORS | OGD | CDER | FDA	3:55 – 4:00 pm