CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

WEBINARS

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Redesigned Pre-Submission Meetings in GDUFA III: Benefits for ANDA Submission and Approval

May 9, 2024, 1:00 – 3:30 pm EDT

Welcome (5 min)	**Welcome and Overview** Nora Lim, *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)	1:00 – 1:05 pm
Talk #1 (20 min)	**GDUFA III Redesigned Pre-Submission Meeting: Overview, Process, and What's New?** Karen Bengtson, *Supervisory Regulatory Health Project Manager* Office of Research and Standards (ORS)| Office of Generic Drugs (OGD) |CDER	1:05 – 1:25 pm
Scenario Discussion (60 min)	**Pre-Submission Meetings: Scenario Discussion** Yan Wang, PhD, *Lead Pharmacologist* Division of Therapeutic Performance I | ORS | OGD | CDER Eleftheria Tsakalozou, PhD, *Senior Pharmacologist & Acting Team Lead* Division of Quantitative Methods and Modelling | ORS | OGD | CDER	1:25 – 2:25 pm
Panel Discussion (30 min)	**Moderator:** Yan Wang, PhD **Panelists:** • Pahala Simamora, PhD, *Division Director*, Division of Product Quality Assessment (DPQA IX), Office of Product Quality Assessment II (OPQA II), Office of Pharmaceutical Quality (OPQ) • Partha Roy, PhD, *Director,* Office of Bioequivalence (OB) | OGD | CDER • William (Bill) Chong, MD, Director, Office of Safety and Clinical Evaluation (OSCE) | OGD | CDER • Robert Lionberger, PhD, Director, ORS|OGD|CDER	2:25 – 2:55 pm
Speaker Q&A Discussion (30 min)	**Moderator:** Nora Lim Speakers and Panel Members: • Karen Bengtson • Yan Wang, PhD • Eleftheria Tsakalozou, PhD • Pahala Simamora, PhD • Partha Roy, PhD • William (Bill) Chong, MD • Robert Lionberger, PhD	2:55 – 3:25 pm
Closing Remarks (5 min)	**Closing Remarks** Robert Lionberger, PhD, Director, ORS|OGD|CDER	3:25 – 3:30 pm