CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

WEBINARS

www.fda.gov/CDERSBIALearn

A Deep Dive: GDUFA III Scientific Meetings

May 15, 2023, 1:00 – 4:30 pm EDT

Welcome (10 min)	Welcome and Overview - SBIA	1:00 - 1:10 pm
Opening Remarks (15 min)	**Introduction to GDUFA III Meetings** Lei Zhang, PhD Deputy Director, Office of Research and Standards (ORS) Office of Generic Drugs (OGD) Center for Drug Evaluation and Research (CDER)	1:10 - 1:25 pm
Talk 1 (25 min)	**GDUFA III Redesigned Pre-Submission Meetings** Karen Bengtson Supervisory Regulatory Health Project Manager, ORS|OGD|CDER	1:25 - 1:50 pm
Talk 2 (25 min)	**GDUFA III Post-Complete Response Letter (Post-CRL) Scientific Meetings** Tao Bai, PhD Senior Advisor, Office of Bioequivalence (OB)|OGD|CDER	1:50 - 2:15 pm
Break (15 min)	Break	2:15 - 2:30 pm
Admin (5 min)	Administrative Reminders - SBIA	2:30 - 2:35 pm
Talk 3 (25 min)	**GDUFA III Product-Specific Guidance (PSG) Teleconferences** Caliope Sarago, MHSA Senior Regulatory Health Project Manager, ORS|OGD|CDER	2:35 - 3:00 pm
Talk 4 (25 min)	**GDUFA III Product-Specific Guidance (PSG) Meetings** Hee Sun Chung, PhD Lead Pharmacologist, Division of Bioequivalence I (DB I)|OB|OGD|CDER	3:00 - 3:25 pm
Q&A and Panel Discussion (60 min)	Moderator: SBIA Staff <u>Panelists:</u> Speakers and: • Rob Lionberger, PhD, Director, ORS|OGD|CDER • Partha Roy, PhD, Director, OB|OGD|CDER • Pinaki Desai, PhD, Senior Biologist, Office of Lifecycle Drug Products (OLDP)|Office of Pharmaceutical Quality (OPQ)|CDER • John Ibrahim, PharmD, BCPS, Associate Director of Regulatory Affairs, Office for Regulatory Operations (ORO)|OGD|CDER • David Coppersmith, JD, Division of Policy Development (DPD)|Office of Generic Drug Policy (OGDP)|OGD|CDER	3:25 - 4:25 pm
Closing Remarks (5 min)	Rob Lionberger, PhD, Director, ORS|OGD|CDER	4:25 - 4:30 pm