Product-Specific Guidances: Lighting the Development Pathway for Generic Drugs

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Speaker/Panelist Bios, in the order of appearance:

Lei Zhang, Ph.D.
Deputy Director
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)
CDER | US FDA

Dr. Lei Zhang serves as deputy director of the Office of Research and Standards (ORS) within the Office of Generic Drugs. ORS implements the Generic Drug User Fee Amendments (GDUFA) science and research commitments to ensure the therapeutic equivalence of generic drug products. Dr. Zhang is an accomplished professional with more than 22 years of combined experiences in the areas of drug research, development, and regulatory review and approval. She has contributed to numerous guidance development and research projects focused on science-based regulatory decision making. Before joining FDA in 2002, she worked at Bristol Meyers Squibb Company as a research investigator and preclinical candidate optimization team leader. Dr. Zhang is an adjunct professor in the Department of Bioengineering and Therapeutic Sciences, University of California at San Francisco (UCSF), Schools of Pharmacy and Medicine. Dr. Zhang received her Ph.D. in biopharmaceutical sciences from UCSF. She is a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Generic Drug Discussion Group (GDG), serving as the U.S. FDA Topic Lead. Additionally, she is the rapporteur for the ICH M13 Expert Working Group that is developing M13 guidelines to harmonize bioequivalence study design for immediate-release oral dosage form drugs. Dr. Zhang was named American Association of Pharmaceutical Scientists (AAPS) Fellow in 2013.

CDR Christine Le, Pharm.D., PMP
Acting PSG Program Manager
Office of Research and Standards (ORS)
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Commander (CDR) Christine Le joined the Office of Research and Standards (ORS) in January 2017 as a senior regulatory project manager. Throughout her work in ORS, CDR Le is instrumental in policy, process development and implementation of the Pre-ANDA Program under GDUFA. CDR Le also serves as a subject matter expert and provides project management support for collaboration and engagements of the CDER offices involved in the Pre-ANDA Program. CDR Le received her Doctor of Pharmacy (Pharm.D.) from the Bernard J. Dunn School of Pharmacy, Winchester, VA in

2001 and a Project Management Professional (PMP) certification in 2015. She has more than 19 years' experience as a hospital pharmacist in Virginia.

Myong-Jin (MJ) Kim, Pharm.D.
Acting Division Director
Office of Research and Standards (ORS)
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Dr. Myong-Jin (MJ) Kim currently serves as the acting director of the Division of Therapeutic Performance II within the Office of Research and Standards. Since joining the Office of Generic Drugs in 2016, Dr. Kim has been leading the efforts to develop product-specific guidances for solid oral dosage forms. In addition to her efforts in product-specific guidance development, she serves as the FDA deputy topic lead for the ICH Expert Working Group on M13: Bioequivalence for Immediate Release Solid Oral Dosage Forms. Dr. Kim graduated from Georgia Institute of Technology in Atlanta, GA, with a Bachelor of Science in chemistry. Subsequently, she received a Doctor of Pharmacy from the Temple University School of Pharmacy in Philadelphia, PA and completed her postdoctoral training in Clinical Pharmacology at Bassett Healthcare (a major teaching affiliate of Columbia University of Physicians & Surgeons) in Cooperstown, NY.

Markham Luke, M.D., Ph.D.
Division Director
Office of Research and Standards (ORS)
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Dr. Markham C. Luke serves as FDA supervisory physician (dermatology) and director of the Division of Therapeutic Performance I (DTP I) in the Office of Research and Standards. This division is responsible for facilitating pre-application development of generic drugs by conducting and promoting regulatory science research to establish standards to ensure therapeutic equivalence of new generic drug products. Dr. Luke has been at FDA since 1998 serving various roles, including as the lead medical officer for dermatology drugs in the Office of New Drugs at CDER, chief medical officer and deputy director for the Office of Device Evaluation in CDRH, and acting director for cosmetics in CFSAN. Dr. Luke has an M.D. and a Ph.D. in Pharmacology from Johns Hopkins University. He completed internal medicine training at Johns Hopkins Bayview Medical Center and a dermatology residency and fellowship at Washington University, St. Louis, MO and at NCI/NIH, Bethesda, MD. Dr. Luke is an associate professor in dermatology at the Uniformed Services University of the Health Sciences, Bethesda, MD. He has research interests in dermato-pharmacology, clinical pharmacology, product innovation and design – especially for combination drug-device products, clinical study design, and endpoints assessment (including patient-reported outcomes) for medical, surgical, and aesthetic products, and serves as consultant dermatologist to various parts of FDA.

Mitchell Frost, M.D.
Acting Deputy Division Director
Office of Research and Standards (ORS)
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Dr. Mitchell Frost serves as acting deputy director in the Division of Therapeutic Performance II within the Office of Research and Standards (ORS). Since joining ORS in 2016, Dr. Frost has been helping to oversee GDUFA-funded clinical

research and to manage clinical issues related to product-specific guidance development and pre-application support. One of Dr. Frost's main focuses is on the protection of human subject participants of clinical studies. He has served on FDA's Institutional Review Board (IRB) and currently serves as a human subject protection liaison to the FDA IRB and the Office of the Chief Scientist.

Paramjeet Kaur, Ph.D.
Senior Reviewer **i**
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)
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Dr. Paramjeet Kaur is a senior reviewer in the Division of Bioequivalence II (DB II) within the Office of Bioequivalence. Since joining DB II in 2008, she has been involved in the assessment of bioequivalence reviews, controlled correspondences, and development of product-specific guidances. She received her Bachelor of Pharmacy from the Banaras Hindu University, India, and Doctorate in Industrial Pharmacy from St. John's University, NY.

Dave Coppersmith, J.D.
Regulatory Counsel
Office of Generic Drug Policy (OGDP)
Office of Generic Drugs (OGD)
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Dave Coppersmith is a regulatory counsel in the Office of Generic Drug Policy. Before joining the Office of Generic Drugs in May 2019, he was a supervisory regulatory counsel in FDA's Center for Tobacco Products' Office of Compliance and Enforcement. Mr. Coppersmith received his B.A. in economics and political science from St. Mary's College of Maryland and his J.D. from the University of Baltimore School of Law.

Robert Lionberger, Ph.D.
Director
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD)
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Dr. Robert Lionberger serves as director of the Office of Research and Standards. In this role, Dr. Lionberger leads the Office of Generic Drugs' implementation of GDUFA regulatory science commitments including internal research activities and external research grants and collaborations to ensure the therapeutic equivalence of generic drug products. In his 10 years as member of the office's science staff, his accomplishments include the development of bioequivalence methods for complex and locally-acting drugs, mathematical modeling of drug dissolution and absorption, and incorporation of pharmaceutical development information into the ANDA review process. He received his undergraduate degree from Stanford University in chemical engineering and a Ph.D. from Princeton University in chemical engineering, working on modeling the rheology of colloidal suspensions. After obtaining his Ph.D., he spent two years of post-doctoral research in Australia in the Department of Mathematics and Statistics at the University of Melbourne. Prior to joining FDA, he was an assistant professor of chemical engineering at the University of Michigan.

Non-Speaker Panelist:

Bing Li, Ph.D.
Acting Associate Director for Scientific Innovation
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD)
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Dr. Bing V. Li serves as acting associate director for scientific innovation in the Office of Bioequivalence. In this role, she provides scientific leadership and expertise for the assessment of bioequivalence studies submitted by pharmaceutical industry through ANDAs, and oversees the scientific programs, including guidance development and implementation, in the Office of Bioequivalence. Dr. Li is an expert pharmacologist at FDA in the area of bioequivalence of aerosolized drug products. Prior to joining FDA in 2004, she was a research investigator at Bristol Myers Squibb where her responsibilities included formulation identification, development, and optimization for oral solid dosage form formulations. Dr. Li received a bachelor's degree in medicinal chemistry in 1990 from Beijing University, China and a Ph.D. in pharmaceutical sciences from the University of Wisconsin at Madison in 2001.